A STUDY ON DRUGS FOR TREATING ANAEMIA
(A Campaign for Access to Essential Drugs)
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YET THERE ARE NO RATIONAL DRUGS TO TREAT ANAEMIA

JOIN DAF-K’s CALL FOR ACTION

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WHAT AILS THE INDIAN DRUG INDUSTRY IS BEST WITNESSED IN THE PLETHORA OF IRRATIONAL PREPARATIONS AVAILABLE FOR THE TREATMENT OF ANAEMIA

In India 95% of adolescent girls and 92.2% of children below 5 years are affected with anaemia!
Main findings of the study

- Anaemia is an extremely common problem and a major public health problem in several developing countries including India. In India more than 50% of the population is affected with anaemia and in several population sub-groups such as adolescents as high as 95% are suffering from it. Anaemia particularly strikes women and children. As per the Essential Drugs List of India and the World Health Organisation, the drugs needed to treat anaemia are a combination of iron with folic acid or a single iron preparation in correct doses. Internationally renowned standard text books of medicine have also advocated the same.

- After screening 338 drugs to treat anaemia from a popular doctors’ reference drug guide book (CIMS-Current Index of Medical Specialities Oct 2005-Jan 2006), it revealed that there is just one drug that fits into the standards prescribed by the Essential Drugs Lists of India and the World Health Organisation (WHO). Many of the drugs listed, to treat anaemia; in the doctors’ popular publication contained substances never advocated in any standard text books of medicine. Some even contained alcohol, liver extract and haemoglobin! The one drug that does fit into the standards prescribed by the WHO is NOT easily available at most chemists’ outlets, for the simple reason that it does not offer much margin of profit.

- The study observed that the cost of medicines to treat anaemia ranges from Rupees 0.13 per tablet to Rupees 6.97 per tablet, which works out to be as low as Rupees 11.70 to as much as Rupees 660 for a treatment period of 30 days. It was also observed that anaemia patients spend anywhere from a minimum of 2 to 56 times more than what they ought to.

- Even though the Indian drug industry has become a major global power in drug production it has not grown to meet the needs of this country, hence a vast majority of the population does not have access to essential medicines. This situation holds good for drugs to treat anaemia as well. As per the Government of India figures, the Indian drug manufacturers had a turnover of Rupees 500,000 million during the year 2003-2004. The above estimates show that we need approximately Rupees 5,850 million to treat 50% of the Indian population of nearly 1,000 million for a treatment period of 30 days with antianaemia medicines. This works out to about 1.17 % of the total annual turnover of the Indian drug Industry.

- *THE ENTIRE NATION IS FACING A SEVERE SHORTAGE OF DRUGS TO TREAT ANAEMIA – EVEN AT THE GOVERNMENT OUTLETS. THIS IS AN UTTER FAILURE IN MANAGEMENT AND LOGISTICS BY BOTH STATE AND CENTRAL GOVERNMENTS. A MATTER OF SHAME! A BIG SCANDAL!!* This is true even when there have been adequate resources available at all levels – state, national and international.
There are nearly 13,500 chemists and druggists outlets throughout Karnataka state. It is projected from limited data that there is a total drug sale of around Rupees 1.74 billion per month that includes the sale of haematinic preparations of around Rupees 96.5 million per month in Karnataka State alone.

In spite of the plethora of drugs in the market our limited study observed that most doctors preferred to stick to a few brand preparations.

In our correspondence with drug manufacturers we observed that drug companies have misused and abused scientific information, so that they could sell unnecessary and fanciful preparations at a higher price.

FROM ALL THESE OBSERVATIONS WE STRONGLY FEEL THAT THIS IS AN IMPORTANT AND URGENT ISSUE FOR ALL GROUPS FIGHTING FOR HUMAN RIGHTS AND ACCESS TO ESSENTIAL MEDICINES.

Join DAF-K’s call for action. Contact DAF-K at 
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STUDY ON DRUGS FOR TREATING ANAEMIA. (As listed in a commercial publication for doctors’ use)
By Dr Gopal Dabade, Dr R R Kongovi, Dr S L Pawar and Dr A N Kabbur.

The study is an attempt to bring to the notice of consumer action groups, the plethora of antianaemia drugs available for the treatment of anaemia in India. It gives sound guidance on selecting rational antianaemia preparations and reveals the inaction by the state authorities towards making these essential drugs available to the people who need them. It also reveals the profit maximising behaviour of the drug industry which includes the promotion of irrational, sometimes harmful and expensive medicines to the unsuspecting and helpless consumer.

Date ……………

By:–
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Cost Rupees **********

MAIN POINTS
1. Anaemia is a state of having a less than normal quantity of haemoglobin. The normal haemoglobin range is from 11 gm % to 13 gm %. Haemoglobin is a pigment that gives the red colour to blood and is responsible for transporting oxygen from the lungs to different parts of the body and bringing carbondioxide to the lungs. In fact anaemia is an excellent indicator of poor nutrition and health status of any community or country.

2. There are several causes for anaemia. Amongst them the commonest cause is nutritional anaemia which is rampant in India. According to a study done by DLHS-RCH, an acronym for Delhi Health Survey Services – Reproductive & Child Health, survey 2002-2003, 95% of adolescent girls in India suffer from anaemia. The same survey states that 92.2% of children below 5 years are anaemic. All this has a devastating effect on the health and growth of adolescent girls and children.

3. This study examines the type of drugs that are available for a doctor to prescribe for the treatment of anaemia. Ideally one would expect and think that there will be rational drugs to treat anaemia. But, No! This study shows and proves that there are virtually no rational drugs to treat anaemia.

4. The study listed all the drugs mentioned in the CIMS, an acronym for Current Index of Medical Specialities of Oct 2005-Jan 2006, as preparations available for the treatment of anaemia. CIMS is a popular commercial publication used
by doctors all over India. In total the drug guide listed 338 drugs in this category. These were compared with a standard text book of Pharmacology "The Pharmacological Basis of Therapeutics", 10th Edition by Goodman & Gilman, World Health Organisation’s List of Essential Drugs 2005 and the Indian List of Essential Drugs 2003. Do the drugs listed in the CIMS, match (with regards to its active ingredients and their quantities) with the standard text book and Essential Drugs Lists of the WHO and India? This exercise was done for all the 338 drugs listed in the CIMS as preparations available to treat anaemia.

5. The scan of the 338 haematinic preparations in the CIMS list revealed that only one drug, namely ferrous fumarate, 200 mg tablet conforms to the WHO List of Essential Drugs, 2005 and the above mentioned other scientific publications, in terms of active ingredients and their quantities. It is also priced at Rupees 0.13 or 13 paise, the lowest priced drug to treat anaemia and a rational drug. But to our dismay we found that this drug ferrous fumarate was NOT available with any chemist in our neighborhood (urban areas of Dharwad town, Karnataka State, South India). Why? Because the drug was so low priced that the profit margin was minimal.

6. VIRTUALLY THE CONSUMER IS LEFT WITH NO CHOICE BUT TO CONSUME DRUGS THAT ARE IRRATIONAL. Drugs that do not match with those recommended in standard text books of medicine. AND UNNECESSARILY COSTLY. FEW OF THEM ARE EVEN HARMFUL.

7. As there are no rational drugs to treat anaemia, doctors are compelled to prescribe drugs which have irrational combinations i.e., that are NOT mentioned in standard text books of medicine and in addition are costly.

8. A price assessment of the drugs listed in CIMS also showed that most of the irrational preparations were also over priced.

9. The Government of India figures reveals that the Indian drug manufacturers had a turnover of Rupees 500,000 million during the year 2003-2004. Our study estimates that we need approximately Rupees 5,850 million for a treatment period of 30 days to treat 50% of the Indian population of nearly 1,000 million with the rational antianaemia preparation. This works out to a mere 1.17% of the total annual turnover of the Indian drug industry.

WAY FORWARD
The Ministry of Petroleum and Chemicals, Government of India, New Delhi, the Ministry responsible for the implementation of the drug policy of India, at the central level should make it mandatory for every drug company to manufacture a certain quantity of rational iron containing medicines. These are drugs that contain active ingredients and quantities as mentioned in the WHO List of Essential Drugs and standard text books of pharmacology. Similarly the State government should make it mandatory for every chemist to keep a minimum quantity of iron containing medicines, which are rational. This issue should be taken up by various consumer groups to pressurise the government, policy makers and industry into action. DAF-K hopes that this booklet will pave the way for such a process through debate and discussion.
In the US drug companies are given tax exemptions etc, if they manufacture a drug that is required for only a small section of the population. These drugs are referred to as ‘Orphan Drugs’. The Government of India should take cue from this mechanism to ensure availability and accessibility of essential drugs with low prices and low profit margins to all who need them.
A STUDY ON DRUGS FOR TREATING ANAEMIA
LISTED IN A COMMERCIAL PUBLICATON FOR DOCTORS’ USE

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PREFACE
FORWARD

1. INTRODUCTION

Nutritional anaemia is a common condition and a major public health problem that needs special attention. Iron deficiency in food intake is the most common cause of nutritional anaemia in human beings. Worm infestations, blood loss and pregnancy also result in nutritional anaemia and are thus related to iron deficiency in humans. The undesirable effects of nutritional anaemia are several, which includes maternal and infant mortality. Anaemia is also associated with complications of the unborn child and mother, such as birth of low weight babies, premature births and bleeding during delivery of child. It also diminishes the work capacity of people and has economic consequences in terms of suboptimal labour.

The study is mainly aimed at equipping consumer and women’s groups actively campaigning and lobbying to build awareness on rational drugs among consumers. It is also meant to provide evidence and influence policy makers on the need for and promotion of rational drug policies. The methodology and the format of the study has been purposely kept simple, so that consumers can easily follow and even use this pattern for a study of another group of drugs.

Drug Action Forum-Karnataka (an independent, non-profit and non-governmental organization campaigning for rational drugs and policies) through this study attempts to bring to the notice of the consumer, about the types of drugs that are commonly manufactured and promoted by drug companies to doctors to treat anaemia. A commercial publication, namely CIMS (Current Index of Medical Specialities) Oct 2005-Jan 2006 used exclusively by doctors was referred to obtain a list of drugs that are promoted by various drug manufacturers to treat anaemia. Consequent to the study Drug Action Forum – Karnataka feels that drugs to treat anaemia should be accessible to all those who need them. Unfortunately this is currently NOT the case.

2. GENDER AND ANAEMIA

Anaemia can occur in both men and women at any stage of their lives, but it clearly has a gendered face. It is estimated that about 450 million women worldwide (WHO 2000) suffer from iron deficiency anaemia. It is not only the physical and biological differences that make women more susceptible to anaemia but the operating inequalities in the social and economic spheres, like inequitable distribution of resources in households and the generally lower income status of women disproportionately depriving women and their children of good health. Hence, vulnerability and impact of anaemia is greater among women of all age groups - infants, adolescents, adults and the elderly as they tend to receive less care and rest. Undernourishment manifests in women and children through micro-nutritional deficiencies like iron-deficiency anaemia, iodine deficiency disorder, goiter etc. Women and children catch infections easily because anaemia lowers their general resistance. 60% of women in India suffer from anaemia
according to the National Human Development Report 2001. Rates of anaemia in India range from 63% in Bihar and Orissa to 22% in Kerala with the other states averaging around 50% as reported by NFHS (National Family Health Services) 1998-99.

Anaemia poses a greater risk for women who are of child-bearing age or are going through a phase in pregnancy. This is because the iron reserves in the body are depleted more rapidly due to the loss of blood that occurs during menstruation, or the increased demand for it needed for the development of the foetus. Severe iron deficiency anaemia therefore, makes pregnancy and delivery not only high-risk events, but often leads to maternal and even perinatal death. Anaemia among women accounts for a significant loss of productivity, and therefore of family welfare, in developing countries. Normally men lose only 1 mg of iron every day (14 µg/kg/day), which is easily replenished through the diet. Such losses are proportionally less in women (0.7 to 0.8 mg/day) but menstrual bleeding causes an additional loss of 0.4 to 0.5 mg iron daily amounting to a total loss of 30 µg/kg/day. It is difficult to treat a severely iron deficient pregnant woman and provide for increased foetal needs through oral iron supplementation alone during the relatively short period of pregnancy. As a public health measure, prolonged supplementation of iron before pregnancy is a better step.

Both due to poverty and socio-cultural reasons, women do not eat sufficient amounts of food, nor is their diet balanced. Many women frequently complain of general aches and pains, a result of physical overwork and strain. Irrespective of social class or geography, back pains, headaches, joint pains and chest pains are universally experienced by women and are related to anaemia, but are actually ignored by women themselves and their family members\(^1\).

### 3. SOME SCIENTIFIC FACTS ABOUT ANAEMIA

#### 3.1 What is anaemia and diet source of iron

Anaemia is a condition in which there aren't enough healthy red blood cells to carry adequate oxygen to the tissues. The body needs a good supply of oxygenated blood to provide energy to function healthily and the lack of it makes a person feel tired.

Blood performs a number of crucial functions, including transporting oxygen throughout the body. Blood consists of liquid called plasma. Floating within this plasma are three types of blood cells — red blood cells, white blood cells and platelets. White blood cells fight infection. Platelets help blood clot after a cut and prevent bleeding. Red blood cells (erythrocytes), which are the most abundant of the three types, give blood its red color. Red blood cells contain haemoglobin — a red, iron-rich protein. Haemoglobin enables red blood cells to carry oxygen from the lungs, via the bloodstream, to the brain and the other organs and tissues of the body.

Most blood cells, including red blood cells, are produced regularly in the bone marrow — a red, spongy material found within the cavities of many of the large bones. Anaemia is a state in which the number of red blood cells or the haemoglobin in them is below normal (the normal haemoglobin range is 11 gm % to 13 gm %) When a person is anaemic, the body produces too few healthy red blood cells, loses too many of them or destroys them faster than they can be replaced. As a result, the blood does not have
adequate red blood cells to carry required levels of oxygen to the tissues — leaving the person fatigued.

3.2 Types of anaemia

Many types of anaemia exist, each with its own cause like an iron or vitamin deficiency, blood loss, a chronic illness, or a genetic or acquired defect or disease. It may also be a side effect of certain drugs. But the commonest type of anaemia is nutritional anaemia. Anaemia can be temporary or long standing. It can range from mild to severe.

Common types of anaemia and their causes include:

**Iron deficiency anaemia.** Anaemia can be caused by a shortage of the mineral iron in the body. The bone marrow needs iron to make haemoglobin. The body cannot produce adequate haemoglobin required for red blood cells to be healthy without adequate quantities of iron available to the bone marrow. The result is iron deficiency anaemia. Iron is also recycled from old red blood cells. Women losing excessive blood during menstruation are at risk of iron deficiency anaemia. Any slow, chronic blood loss from a source within the body — such as an ulcer, a colon polyp or even colon cancer — can lead to iron deficiency anaemia. An iron-poor diet or an inability to absorb iron from foods due to an intestinal disorder or surgery to the intestines can lead to this anaemia. In pregnant women, a growing foetus can deplete the mother's store of iron, leading to iron deficiency anaemia.

**Vitamin deficiency anaemia.** In addition to iron, the body needs folic acid and vitamin B-12 to produce sufficient healthy red blood cells. A diet lacking in these and other key nutrients can cause decreased red blood cell production leading to anaemia.

**Anaemia of chronic disease.** Certain chronic diseases, such as AIDS, cancer, liver disease and chronic inflammatory diseases can interfere with the production of red blood cells, resulting in chronic anaemia. Kidney failure also can be a cause of anaemia. The kidneys produce a hormone called erythropoietin, which stimulates the bone marrow to produce red blood cells. A shortage of erythropoietin — which can result from kidney failure or be a side effect of chemotherapy — can result in a shortage of red blood cells.

**Aplastic anaemia.** This is a life-threatening anaemia caused by a decrease in the bone marrow's ability to produce all three types of blood cells — red blood cells, white blood cells and platelets. A serious infection — such as hepatitis, exposure to toxic chemicals or certain medications can trigger aplastic anaemia.

**Haemolytic anaemia.** This group of anaemia develops when red blood cells are destroyed at a faster rate due to autoimmune disorders than the rate that bone marrow can replace them. Certain blood diseases as well as medications used to treat infections can cause increased premature red blood cell destruction. Haemolytic anaemia may cause yellowing of the skin (jaundice) and an enlarged spleen.
**Sickle cell anaemia.** This inherited and serious anaemia affecting mainly black people of African origin is caused by a defective form of haemoglobin that forces red blood cells to assume an abnormal crescent (sickle) shape. These irregular-shaped red blood cells die prematurely, resulting in a chronic shortage of red blood cells.

**3.3 Symptoms of anaemia. The main symptom of most anaemia is fatigue.** Other signs and symptoms of anaemia include weakness, pale skin, including decreased pinkness of the lips, gums, lining of the eyelids, nail beds and palms, rapid heartbeat with mild exertion, shortness of breath with mild exertion, chest pain, dizziness, irritability (in children with anaemia), numbness or coldness in hands and feet.

**3.4 Implications of anaemia**

Several studies have indicated that iron deficiency and iron deficiency anaemia could lead to health and cognitive impairment problems, notably in infants, children, adolescents, women of reproductive age, pregnant women, adults, and the elderly. Infants born of mothers with iron deficiency anaemia are likely to have low iron stores and thus are in need of more iron than can be supplied by breast milk. There is convincing evidence linking iron deficiency anaemia to lasting effects like lower cognitive test scores. There are numerous references showing a negative relationship between iron deficiency anaemia and physical and mental activity, workplace and school productivity of older children and adults. As per K Park’s Textbook of Preventive & Social Medicine 2005 (18th edition, page 449) “Iron is necessary for many functions in the body including formation of haemoglobin, brain development and functions, regulation of body temperature, muscle activity and metabolism”. Moreover, “Iron has an important role in the function of nerve cells. Having a sufficient amount of available iron is important for infants and young children, whose brain and other nerve cells are growing rapidly”, states Sue Rodwell Williams & Eleanar D. Schlenker's in their publication “Essentials of Nutrition & Diet Therapy” (8th edition page 199).

**Pregnant women**

Iron deficiency during pregnancy is extremely common even among otherwise well-nourished populations. Severely anaemic pregnant women are at greater risk of death during the perinatal period.
**Anaemia a silent epidemic in India**

- More than 2 billion dollars are lost per year due to the loss of man hours and productivity due to anaemia.
- Anaemia is responsible for 40% of 100,000 maternal deaths that occur per year due to complications of pregnancy and childbirth.
- Over 90% of adolescents in Delhi are anaemic. *(Delhi Gynecologists Forum)*
- Only 35.10% of pregnant mothers receive prophylaxis against nutritional anaemia. *(Annual Report MOHFW 2002/03)*
- 9 out of 10 adolescents, children and pregnant women in India are anaemic. *(DLHS RCH Survey 2002/2003)*

Persons with iron deficiency anaemia generally suffer from impaired cognitive performance, morbidity from infectious diseases, reduced ability to monitor and regulate body temperature when exposed to cold temperatures as well as significant reduction of physical work capacity.²
Figure 3.4.1
Anaemia among adolescent (Age between 10 - 19 years) girls in India


3.5 Treatment of anaemia with oral iron.

Iron is an important constituent of haemoglobin as each molecule of it contains four atoms of iron amounting to 1.1mg of iron per milliliter of red blood cells. An adult man requires on an average 14µg/kg/day. This is equivalent to about 1mg per day; however, a menstruating woman requires about 30 µg/kg/day which is about 1.4mg per day. Pregnant women in the last two trimesters require nearly 80 µg/kg/day which is about 5-6 mg per day. Anaemic patients are prescribed iron preparations to overcome their iron deficiencies and associated medical problems.

It is well established that orally administered ferrous sulphate is the treatment of choice for iron deficiency and also the most economical. Absorption of ferrous salts is three times the absorption of the corresponding ferric salts. It is also observed that sulphate, succinate, gluconate, fumarate and other ferrous salts are absorbed in the body to approximately the same extent. Ferrous sulphate hydrate contains 20% elemental iron, dried ferrous sulphate has 32% iron, ferrous fumarate 33% and ferrous gluconate 12% iron. Polysaccharide-iron complex is another preparation being used in the treatment of iron deficiency anaemia. The amount of iron, rather than the mass of the total salt in the tablets/capsules, is important. It is also to be noted that coating of the tablet should dissolve rapidly in the stomach. Since, iron is usually absorbed in the upper small intestine, certain delayed-release preparations, claiming to be even more effective when taken with meals than ferrous sulphate, are considered questionable.

Some observations about the ineffectiveness of these preparations are noted elsewhere in the report.
Cereals are the most important source of iron in the diets of a large majority of the population in India and other developing countries. Other important sources are legumes, green vegetables and jaggery. Meat, fish and eggs are important sources of iron in all advanced countries. Milk is a poor source of iron\(^3\).

**3.6 Recommended dose of iron for treatment**

It is generally recommended that the average dose for the treatment of iron-deficiency anaemia is about 200mg of iron per day (2-3 mg/kg for infants and children), given in three equal doses of 65 mg. When the objective is the prevention of iron deficiency in pregnant women, doses of 15-30mg of iron per day are adequate to meet the 3-6 mg daily requirement of the last two trimesters. As stated in Goodman and Gilman a total dose of about 100mg per day may be used, in selected cases depending upon the degree of anaemia. Intolerance to iron preparations occurs in about 25% of individuals. Side effects such as heartburn, nausea, upper gastric discomfort, constipation and diarrhoea may occur and this aspect should be considered in the treatment plan.

Treatment of anaemia requires 1 to 2 months therapy with antianaemia drugs. The duration of treatment is governed by the rate of recovery of haemoglobin and the desire to create iron stores. The former depends on the severity of the anemia. With a daily rate of repair of 2 g of haemoglobin per liter of whole blood, the red cell mass usually is reconstituted within 1 to 2 months\(^5\). In this booklet for convenience and practical purposes the calculations have been done for a treatment period of one month (30 days).

Injectable form of iron administration is resorted to only when oral therapy fails to be effective. Iron dextran injection is the injectable preparation in general use\(^5\).

**3.7 Combining iron with other components**

**3.7.1 Iron with Vitamin C**

Goodman & Gilman in the Chapter entitled ‘Drugs acting on the blood and blood forming organs’ in the eleventh edition of “The Pharmacological Basis of Therapeutics” state: “A variety of substances designed to enhance the absorption of iron has been marketed; including surface-acting agents, carbohydrates, inorganic salts, amino acids, and vitamins. One of the more popular of these is ascorbic acid. When present in an amount of 200mg or more, ascorbic acid increases the absorption of medicinal iron by at least 30%. However, the increased uptake is associated with a significant increase in the incidence of side effects. One particularly harmful side effect is the destruction of the intestinal mucous membrane (inside lining of the intestine) when put to over work.

Therefore, the addition of ascorbic acid seems to have little advantage over increasing the amount of iron administered. It is inadvisable to use preparations that contain other compounds, with therapeutic actions of their own, such as Vitamin B-12, folate or cobalt, since the patient’s response to the combination cannot be easily interpreted\(^5\).
3.7.2 Iron with Copper, Pyridoxine and Riboflavin.

Anaemia due to copper deficiency has been described as a complication in certain cases. Copper deficiency is extremely rare in human beings. The amount present in food is more than adequate to provide the needed body requirement of nearly 900 microgram of copper per day. Copper deficiency usually occurs concurrently with multiple nutritional deficiencies, so that its specific role in the production of anaemia may be difficult to ascertain.

It is stated that oral treatment with pyridoxine is of proven benefit in correcting anaemias associated with consumption of anti-tuberculosis drugs isoniazid and pyrazinamide.

The spontaneous appearance in human of red cell aplasia due to riboflavin deficiency undoubtedly is rare, if it occurs at all. It has been described in combination with infection and protein deficiency, both of which are capable of producing hypoproliferative anaemia.

3.7.3 Iron with Vitamin B-12, Folic Acid and the Treatment of Megaloblastic Anaemia

Vitamin B 12

It is widely recognized that Vitamin B-12 and folic acid are dietary essentials. An early sign of deficiency of these vitamins is megaloblastic anaemia. Abnormal macrocytic red blood cells are produced and patients become severely anaemic and this condition is generally referred to as pernicious anaemia. Vitamin B-12 is available in pure form for injection or oral administration or in combination with other vitamins and minerals for oral or parenteral administration. Oral preparations are of relatively little value in the treatment of patients with deficiency of intrinsic factor. Pernicious anaemia is caused by the absence of intrinsic factor normally present in the gastric juice and necessary for absorption of B-12. A person with defective Vitamin B-12 absorption and hence pernicious anaemia can be adequately maintained with monthly intramuscular injection of 1000 micrograms of vitamin. The oral route cannot be relied upon for effective therapy in the patient with a marked deficiency of Vitamin B-12. Thus, cyanocobalamin (Vitamin B-12) must be administered by intramuscular or deep subcutaneous injection for the treatment of Vitamin B-12 deficiency.

Goodman & Gilman in their above mentioned chapter clearly state: “Vitamin B-12 has an undeserved reputation as a health tonic and has been used for a number of diverse disease states. Effective use of this vitamin however depends on accurate diagnosis and understanding of the various principles and mechanisms involved in the therapy”. “Therapy always should be as specific as possible. While a large number of multivitamin preparations are available, the use of “shotgun” vitamin therapy in the
treatment of Vitamin B-12 deficiency can be dangerous. With such therapy, there is the danger that sufficient folic acid will be given to result in haematological recovery. This can mask continued Vitamin B-12 deficiency and permit neurological damage to develop or progress”.

Deficiencies of B-complex vitamins are suggested to be corrected by increased food intake and severe cases to be treated with specific vitamins on individual basis. Inclusion of vitamins will not only escalate the cost of haematinic preparations, but also create uncertainty as to the specificity of any response obtained. Haematologists have not recommended, but rather universally condemned preparations incorporating B-complex vitamins along with haematinic drugs particularly those with iron and folic acid.

**Folic acid**

As far as its use is concerned the general nature of folic acid is in the same line as Vitamin B-12. Folic acid is recognized as an essential medicine for antianaemia.

**3.7.4 Iron-Polymaltose complex**

The renowned haematologist Prof B C Mehta, previously from Seth G S Medical College, along with KEM Hospital, Mumbai has published a case report on the ineffectiveness of iron hydroxide-polymaltose complex in the treatment of iron deficiency anaemia. Prof Mehta in 1987 had taken up a trial of iron hydroxide-polymaltose for the treatment of iron deficiency anaemia at the Dr J C Patel Department of Haematology, KEM Hospital, Mumbai. It was observed that none of the 21 patients who had completed 3-4 weeks of therapy showed any rise in their haemoglobin levels. None of the patients had any causes to explain the lack of response to iron hydroxide-polymaltose therapy. All the patients responded to ferrous sulphate given orally. In another study Nielsen and coworkers observed no increase in haemoglobin with iron hydroxide-polymaltose in 9 patients who received treatment for 4 weeks; but responded to ferrous sulphate therapy. 
4. METHODOLOGY OF STUDY

The study is considered under the following two main headings:

i. **Rationality:** - Do the drugs listed under the category of ‘Multiple combination haematopietics’ (antianaemics) in the commercial publication CIMS, match (with regards to active ingredients and their quantities) with those of the WHO’s Essential Drug List, National Essential Drugs List of India and standard text books of pharmacology?

ii. **Drug prices:** - Compares the prices of the WHO recommended Essential Drugs with other selected preparations produced by different drug companies and listed in the CIMS.

Four publications (one commercial and three scientific) have been used extensively for this study. One is a commercial publication, widely used by doctors all over India and the other three are scientific publications.

1) **Current Index of Medical Specialities (CIMS)**

A commercial publication, the “Current Index of Medical Specialities” is known popularly by its acronym CIMS. The October 2005-January 2006 issue was used for this study. CIMS lists in its index, 22 groups of drugs under different categories. Drugs listed under “Multiple combination haematopietics” a category under ‘Hematopoietic drugs’ (i.e. drugs to treat anaemia) included in the main group heading ‘Nutrition and Metabolism’ have been considered for this study. These drugs listed for the treatment of anaemia are available in various dosage forms {e.g. tablets, capsule, syrups, powder, kit (Kit is a combination of a tablet and a capsule, each to be taken a day. For example CAFÉ KIT ® by Aristo company contains capsule of Iron & folic acid, while the tablet contains calcium) and injection etc} and in different dosages. In total there were 338 formulations manufactured by 124 drug companies.

2) **WHO Model List of Essential Drugs**

A scientific publication. The WHO Model list of Essential Drugs of March 2005 (accessible at [http://www.who.int/medicines/publications/essentialmedicines/en/](http://www.who.int/medicines/publications/essentialmedicines/en/)) has been used for the purpose of this study. This list contains about 375 drugs in 500 formulations (or dosage forms). These provide safe, effective treatment for the vast majority of communicable and non-communicable diseases. Essential Drugs should be the drugs of first choice, more so in a situation where financial resources are scarce. The list was first published in 1977 by WHO and updated regularly every two years since and has proven that most diseases can be managed with a few carefully selected medicines.

A scientific publication. This is a standard text book which is used for reference and study by academic medical professionals all over the globe.


A list of Essential Drugs drawn up by the government of India.

Both publications i.e. CIMS and the textbook by Goodman Gilman are available at most book sellers.

All 338 drugs listed in the CIMS under multiple combination haematopoietic drugs were systematically scrutinised with reference to the World Health Organization’s Model List of Essential Drugs (to determine inclusion in the WHO’s List), National Essential Drugs List of India and the above mentioned standard text book of Pharmacology.

Box no 4.1 RATIONAL & IRRATIONAL – What do these terms mean?
Both these words have been used frequently throughout this booklet and hence a brief description of these terms is given as they are referred to in the context of this study.

Rational drugs
The term rational is used for drugs that are scientific i.e. their efficacy for a condition is clinically proven and the therapeutic benefits outweigh the risks. Rational drugs finds mention and are recommended in scientific publications such as standard text books of Pharmacology for treating a particular condition. The wide majority of rational drugs contain a single active ingredient.

Irrational drugs
The term irrational is used to describe drugs that are not recommended for treatment of a particular condition in scientific publications. These are drugs that lack good clinical and pharmacological evidence on their therapeutic benefit and safety. Indiscriminate and unproven combinations of active ingredients form a large part of irrational drugs.

The presence of irrational drugs is not only an economic burden but can also be harmful. This is even more so in a developing country like India.
5. RATIONALITY

5.1 Essential Medicines to treat anaemia

5.1.1 Antianaemia medicines in the WHO Essential Medicines List of March 2005 presents a list of the most efficacious, safe and cost-effective minimum medicines needed for a basic health care system. The WHO List of March 2005 mentions the following under the heading “Medicines affecting the blood: antianaemia medicines”.

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ferrous salt</td>
<td>Tablet, equivalent to 60 mg iron; Oral solution equivalent to 25mg iron (as sulphate)/ml.</td>
</tr>
<tr>
<td>Ferrous salt + Folic acid</td>
<td>Tablet equivalent to 60 mg iron + 400 micrograms folic acid (nutritional supplement for use during pregnancy)</td>
</tr>
<tr>
<td>Folic acid</td>
<td>Tablet 1 mg, 5 mg</td>
</tr>
<tr>
<td>Hydroxycobalamin</td>
<td>Injection, 1 mg in 1ml ampoule</td>
</tr>
</tbody>
</table>

5.1.2 Antianaemia medicines in the National List of Essential Medicines 2003 of India mentions the following under “Medicines affecting the blood: antianaemia medicines”:

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cyanocobalamin</td>
<td>Injection 1mg/ml</td>
</tr>
<tr>
<td>Ferrous salt</td>
<td>Tablets Equivalent to 60 mg elemental iron. 25 mg elemental iron (as sulphate)/ml</td>
</tr>
<tr>
<td></td>
<td>Oral solution</td>
</tr>
<tr>
<td>Folic acid</td>
<td>Tablets 1 mg, 5 mg</td>
</tr>
<tr>
<td>Iron dextran</td>
<td>Injection 50 mg iron/ml</td>
</tr>
<tr>
<td>Pyridoxine</td>
<td>Tablets 5 mg</td>
</tr>
</tbody>
</table>
5.2 Rational medicines to treat anaemia

The lone survivor:

Scrutiny of the 338 drugs to treat anaemia listed in CIMS revealed that only one drug, namely ferrous fumarate, 200 mg tablet conforms to the WHO’s List of Essential Drugs 2005, National Essential Medicines List 2003 of India and Goodman & Gilman’s standard text book of Pharmacology, in terms of its active ingredients and their quantities. It is also priced Rupees 0.13 or 13 paise per tablet, the lowest price for any drug to treat anaemia from the list.

But this drug is not available with the chemists’ shops in our neighborhood (town of Dharwad – a district in the state of Karnataka in South India). On further probing the chemist replied that “there was NOT enough margin of profit to sell this product!” This is a good example of a drug that is in the Essential Drugs List of both WHO and the Government of India but is not available in the market.

This is also an example of how market forces are unable to tackle public health needs for certain drugs that are required. As a result there is no choice but for the government to intervene through proper legislation to protect the interests of the people, by making essential medicines available.

Apart from the 338 drugs to treat anaemia studied in this project, there exist in addition several drugs in the market which are not listed in the CIMS. Since there is no track of the drugs registered in the country, nobody really knows the total number of formulations floating in the market to treat anaemia or even the total number of drugs in the Indian market. An approximate calculation places the total number of all formulations in the Indian market at around 80,000. Most of them being irrational combinations!

Unfortunately, this is the appalling situation of the drug regulatory body in India. The consumer should raise this issue with concerned Ministers, political parties and other elected representatives.

The study also revealed that medicines described under 6.1 are some other medicines in the CIMS list, Oct 2005 - Jan 2006, that came close to the requirement in terms of composition recommended by WHO and Goodman & Gilman. However with the exception of ferrous fumarate 200 mg tablet all the other 337 entries are irrational combinations.

6. PRICES OF DRUGS TO TREAT ANAEMIA –

6.1 Cost of treatment with various iron and folic acid preparations.

The cost per day and the cost of treatment for 30 days was calculated for those drugs whose active ingredients and their quantities came close to medicines recommended by the WHO Essential Medicines List. This attempt is to compare the cost of treatment with medicines actually available for use with rational medicines recommended by scientific publications. The cost of treatment for 30 days with the following medicines to treat anaemia, range from Rupees 11.70 to Rupees 540. This is a huge difference of more than 46 times.
<table>
<thead>
<tr>
<th>Name</th>
<th>Composition Iron + Folic acid</th>
<th>Price Rupees per Tab/ml</th>
<th>Reqd/Recommended dose per day</th>
<th>Cost per day in Rupees</th>
<th>Cost of treatment for 30 days</th>
<th>Manufacturer/Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHUFER</td>
<td>100mg + 1000mcg</td>
<td>4.10</td>
<td>2 tabs</td>
<td>8.20</td>
<td>246.00</td>
<td>SERUM INTL</td>
</tr>
<tr>
<td>COFOL</td>
<td>150mg* + 0.5mg</td>
<td>1.80</td>
<td>4 tabs</td>
<td>7.20</td>
<td>216.00</td>
<td>CIPLA</td>
</tr>
<tr>
<td>FE-COM</td>
<td>100mg + 1mg</td>
<td>4.50</td>
<td>2 tabs</td>
<td>9.00</td>
<td>270.00</td>
<td>MAPRA</td>
</tr>
<tr>
<td>FECONTI N-F</td>
<td>100mg + 0.5mg</td>
<td>4.33</td>
<td>Twice a day (R)</td>
<td>4.33</td>
<td>129.90</td>
<td>MODI MUNDI</td>
</tr>
<tr>
<td>FEFOL SPANSUL ES</td>
<td>150mg* + 0.5mg</td>
<td>1.50</td>
<td>4 tabs</td>
<td>6.00</td>
<td>180.00</td>
<td>GSK</td>
</tr>
<tr>
<td>FEONAT</td>
<td>150mg* + 0.5mg</td>
<td>1.50</td>
<td>4 tabs</td>
<td>6.00</td>
<td>180.00</td>
<td>NATCO</td>
</tr>
<tr>
<td>FERICH SR CAPS</td>
<td>150mg* + 1.0mg</td>
<td>1.75</td>
<td>4 tabs</td>
<td>7.00</td>
<td>210.00</td>
<td>PURE HEALTH</td>
</tr>
<tr>
<td>FERICIP TABS</td>
<td>50mg + 350mcg</td>
<td>4.50</td>
<td>4 tab</td>
<td>18.00</td>
<td>540.00</td>
<td>CIPLA</td>
</tr>
<tr>
<td>FERITOP SR</td>
<td>150mg* + 0.5mg</td>
<td>2.33</td>
<td>4 tab</td>
<td>9.32</td>
<td>279.60</td>
<td>IND SWIFT</td>
</tr>
<tr>
<td>FERROUS FUMARATE</td>
<td>200mg* -</td>
<td>0.13</td>
<td>1-3 tabs (R)</td>
<td>0.13-0.39</td>
<td>3.90-11.70</td>
<td>J &amp; J DeChane</td>
</tr>
<tr>
<td>FERULOGIC</td>
<td>100mg + 350mcg</td>
<td>3.90</td>
<td>2 tabs</td>
<td>7.80</td>
<td>234.00</td>
<td>CHEMO</td>
</tr>
<tr>
<td>HEMFER-A SYRUP</td>
<td>50mg + 1mg/5ml</td>
<td>0.30</td>
<td>10 ml (R)</td>
<td>3.00</td>
<td>90.00</td>
<td>ALKEM</td>
</tr>
</tbody>
</table>

* Salt of iron and not elemental iron, hence the calculations follow that of the required dose for the treatment of anemia taken as 200 mg of elemental iron per day.
(R): Dose as recommended by drug company (mentioned in CIMS); all others are calculated dosages.

The following tables provide the prices of the recommended medicines to treat anemia as announced by LOCOST, CDMU and Tamil Nadu Medical services Corporation Limited, Chennai.
6.2 LOCOST India Prices, March 2006

<table>
<thead>
<tr>
<th>Name of medicine</th>
<th>Cost of 1000 tabs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ferrous sulphate + Folic acid Paediatric 67mg +0.1mg</td>
<td>Rupees 35.00</td>
</tr>
<tr>
<td>Ferrous sulphate + Folic acid 200mg + 1mg</td>
<td>Rupees 65.00</td>
</tr>
</tbody>
</table>

6.3 CDMU Prices July 2003-June 2004

<table>
<thead>
<tr>
<th>Name of medicine (Generic)</th>
<th>Cost of 1000 Tabs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ferrous sulphate</td>
<td>Rupees 27.86; 32.44; 32.55</td>
</tr>
<tr>
<td>Ferrous sulphate + Folic acid 200mg+ 500mcg</td>
<td>Rupees 38.58</td>
</tr>
<tr>
<td>Folic acid 5mg</td>
<td>Rupees 75.95; 86.80</td>
</tr>
</tbody>
</table>

6.4 Tamil Nadu Medical services Corporation Ltd; Prices Nov 2003 to March 2005

<table>
<thead>
<tr>
<th>Name of medicine (Generic)</th>
<th>Cost of 1000 tabs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ferrous sulphate + Folic acid (Paed.)</td>
<td>Rupees 49.50</td>
</tr>
<tr>
<td>Ferrous sulphate + Folic acid</td>
<td>Rupees 67.40</td>
</tr>
</tbody>
</table>

6.5 Treatment cost with some irrational preparations
(See chart attached in landscape)

From the above table it can be observed that the cost of medicines to treat anaemia ranges from a low of Rupees 0.13 per tablet (ferrous fumarate) to Rupees 6.97 per tablet (AHB-15). The treatment cost for 30 days vary from a low Rupees 11.70 to as much as Rupees 660.

Based on the contents in the tables on haematinics under 6.1 and 6.5, it can be reasonably determined that anaemia patients spend anywhere from a minimum of 2 to 56 times than what they ought to.
7. HOW DO THESE DRUGS HARM US

Most of us think that vitamins and minerals are good for the body, that these are just “candies” that do not do much harm. But, is this popular belief really true? Certainly not! They harm the body physically by confusing the doctor against the accurate diagnosis of the disease, and they take a heavy toll on the consumers’ pockets.

a. **How they confuse the doctor:** They do so through what is popularly known in the medical field as “shotgun” antianaemia preparations. A large number of antianaemia formulations containing varying quantities of iron, Vitamin B12, folic acid and sometimes other vitamins and nutrients are marketed and promoted. They are liable to be used indiscriminately without a proper investigation into the actual cause of anaemia. **Most preparations contain one or all ingredients in low amounts; thus, an incomplete response can occur when they are used, by masking the disease. This may adversely affect the diagnosis and assessment of the patient in the future**. Also some preparations contain alcohol, which could be harmful to the liver of the children if they are malnourished.

b. **Making holes in patients pockets:** A World Bank document using the NSS (National Sample Survey) data concludes that:

- More than 40% of those hospitalized borrow money or sell assets to meet expenses.
- At least one quarter of hospitalized Indians fall below the poverty line because of hospitalization and related drug costs.
- Only 10% of Indians have some form of insurance which itself is not adequate.

Since only a small segment of the population has health insurance, this results in increased out-of-pocket expenditure for health. It is estimated that out-of-pocket expenditure is highest in India, as high as 83% and the balance meager 17% constitutes government spending. Additionally a substantial proportion of this expense goes towards the purchase of drugs. In India drug costs constitute around 40% to 50% of the cost of treatment.

Irrational and costly iron preparations are just one of many examples that no doubt add to this economic burden.

8. ORPHAN DRUGS

This study reveals that there is a lack of drugs to treat anaemia which is an extremely common condition. The drug industry does not believe in manufacturing rational drugs to treat anaemia as it is not profitable. (See section 9 – How profitable is the Indian drug industry). The only option that remains is for the government to intervene and bring in proper policies and regulations so that drug companies are compelled to manufacture these drugs. A good example of a government intervention to improve access to
medicines at affordable prices to those who need them is the US law on Orphan Drugs. Such an intervention could be applied in India even though the situation in India and the US are completely different. The US through this legislation aims to address the issues of access to medicines for rare diseases affecting a very small proportion of the population while on the other hand a similar government intervention is advocated in India to improve access to medicines to an extremely common condition (nutritional anaemia) affecting a large proportion of the population especially of women and children.

ORPHAN DRUGS ACT IN THE USA

The term “orphan drug” refers to a product that treats a rare disease affecting fewer than 200,000 Americans. The Orphan Drug Act was signed into law on 4th January 1983. Since then, over 100 orphan drugs and biological products have been brought to market (http://www.fda.gov/cder/handbook/orphan.htm).

The intent of the Orphan Drug Act is to stimulate the research, development, and approval of products that treat rare diseases. This mission is accomplished through several mechanisms:

• Sponsors are granted seven years of marketing exclusivity after approval of its orphan drug product.
• Sponsors are also granted tax incentives for clinical research they have undertaken.
• FDA’s Office of Orphan Products Development (http://www.fda.gov/orphan/index.htm) coordinates research study design assistance for sponsors of drugs for rare diseases.
• The Office of Orphan Products Development also encourages sponsors to conduct open protocols, allowing patients to be added to ongoing studies.
• Grant funding is available to defray costs of qualified clinical testing expenses incurred in connection with the development of orphan products.

9. HOW PROFITABLE IS THE INDIAN DRUG INDUSTRY?

The Indian drug industry is a highly profitable industry. The market has witnessed far too many manufacturers than could be imagined. The technological prowess of Indian drug manufacturers needs a mention amongst the developed countries, since there are quite a few manufacturers worth the name.

According to National Pharmaceuticals Policy 2006, PART-A by the Department of Chemicals and Petrochemicals Government of India December 28, 2005:

“Driven by the knowledge skills, growing enterprise, low costs, improved quality and demand (domestic and international) the pharmaceuticals sector has witnessed a tremendous growth over the past few years - from a turnover of Rupees 50 billion in 1990 to over Rupees 5000 billion during 2004-05. Exports have also grown very significantly to over Rupees 167 billion during this period. India is today recognized as one of the leading global players in the manufacture of pharmaceuticals - it holds 4th position
in terms of volume and 13th in terms of value of production. It is also recognized that the cost of drugs produced in India is amongst the lowest in the world. It is estimated that by the year 2010 the industry has the potential to achieve Rupees 1000 billion in formulations with bulk drug production going up from Rupees 80 billion to Rupees 250 billion.

According to a report in the popular magazine “The Week” dated, 16th May 2004 titled “Secrets of India’s Billion Dollar companies”, the consultancy firm McKinsey, prepared Ranbaxy’s Target 2012 report, on which is based Ranbaxy’s vision document. Titled ‘Garuda’, it envisages Ranbaxy becoming one of the world’s top five pharma companies by 2012. The revenue target - $2 billion in three years and the magical $5 billion by 2012. That is approximately Rupees 220 billion at the current dollar rate.

RANBAXY LABORATORIES with its head quarters in New Delhi was established in 1961; with a turnover of Rupees 45.30 billion and a net profit of Rupees 7.13 billion.

It is obvious that the industry has the capacity and the technical know-how to manufacture the drugs needed to treat anaemia. The skill and expertise gained in manufacture need to be utilized for the protection of the poor and the needy from the onslaught of diseases like anaemia. A healthy balanced outlook on the part of the drug manufacturers is called for to consider the social relevance associated with such preparations as antianaemic medicines and to responsibly take up their production although this may not produce voluminous profits.

If the Indian drug industry is amassing so much of profit then one would naturally wonder as to how much it is really benefitting the people of India. According to “Prescription for healthy development; increasing access to medicine 2005” a publication by United Nations Development Report of the Task Force on HIV/AIDS, Malaria, TB, and Access to Essential Medicines, Working Group on Access to Essential Medicines states that “65 percent of Indians and 47 percent of Africans lack access to essential medicines. In Europe that share is 14 percent and in the Americas 22 percent”. For the year 1999 figure 9.1 illustrates the share of people without access to essential medicines by region.
Figure 9.1
Share of people without access to essential medicines, by region, 1999

<table>
<thead>
<tr>
<th>Region or country</th>
<th>% of the population without access to Essential Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>70</td>
</tr>
<tr>
<td>Africa</td>
<td>60</td>
</tr>
<tr>
<td>East Med</td>
<td>50</td>
</tr>
<tr>
<td>SE Asia</td>
<td>40</td>
</tr>
<tr>
<td>America</td>
<td>30</td>
</tr>
<tr>
<td>China</td>
<td>20</td>
</tr>
<tr>
<td>Europe</td>
<td>15</td>
</tr>
<tr>
<td>WP Europe</td>
<td>10</td>
</tr>
</tbody>
</table>


It can be noted that even though the Indian drug industry has become a major global power in drug production it has not grown to meet the needs of this country, as a vast majority of the population do not have access to essential medicines. This situation holds good for drugs to treat anaemia as well.
10. NATIONAL SHAME! NATIONAL SCANDAL!!*

For almost the past two years, the Ministry of Health, Government of India has totally failed to supply iron and folic acid medicines with Sub-center RCH (Reproductive and Child Health) Kit A & B (A kit under this programme is popularly known as Kit A & B) to state Health Departments under the RCH program. At the end of the second year the Central Government having found that it was unable to procure and supply essential medicines, took a U turn, by advising the state governments to buy the needed stock medicines for Sub-center Kit A & B (including iron and folic acid). This was just four months back. The central government agreed to release the necessary money to the states. One fails to understand why the central governments needed two years to release this money!

Till this day none of the states have been able to get the total required quantity of iron and folic acid. In states like Bihar the amount would have been already utilized for some other purpose! In a few states like Karnataka – some efforts have been made to provide iron and folic acid during the mid-day meal for school children (a welfare programme of the state of Kanataka) and to a few Stree Shakti groups (women self help groups – mostly rural). OTHER THAN THAT NO DRUGS HAVE BEEN MADE AVAILABLE TO TREAT ANAEMIA DURING PREGNANCY FOR THE LAST TWO YEARS.

SO VIRTUALLY THE ENTIRE NATION IS FACING A SEVERE SHORTAGE OF DRUGS TO TREAT ANAEMIA – EVEN AT THE GOVERNMENT OUTLETS. THIS IS AN UTTER FAILURE IN MANAGEMENT AND LOGISTICS BY BOTH STATE AND CENTRAL GOVERNMENTS. A MATTER OF SHAME! A BIG SCANDAL!! This is true even when there has been adequate resources available at all levels – state, national and international.

This study on drugs to treat anaemia, also exposed a gamut of other issues.

On an average Rupees.75,000 is given every year to a primary health centre for the purchase of medicines. The annual budget for the Karnataka state for the purchase of drugs is Rupees 750 million annually. This amount is targeted to increase to Rupees 1.25 billion in the next few years. How was this magic figure arrived at? It really remains a magic figure, as there are no studies done in Karnataka (as well in all other Indian states) to determine the disease burden! Depending upon the disease burden one needs to calculate the quantum of drugs needed. The WHO has evolved standard guidelines as to how this assessment of drug requirement can be found out by governments.

The Government of Karnataka seems to have other criteria for choosing the quantity of drugs needed in the state:
1. Three years ago, 18% of Karnataka Health Department’s drug budget was spent on buying nimesulide – a drug that has been banned in several countries – because of its toxic side effects. Still a major part of the budget went to this drug because the manufacturer had good connections with the politicians and bureaucrats.
2. Amongst the list of Essential Drugs not available – it is NOT just iron and folic acid. But includes a whole lot of other essential drugs such as Injection adrenaline
(a life saving drug needed to treat drug reactions), Injection atropine (a drug needed to manage common poisoning), at times paracetamol and many others as well. The total number of such drugs in this list is around thirty!

Why are these essential drugs not available?
When the state government invites drug manufactures for tenders these essential drugs are not picked up by drug manufacturers, as they do not bring in enough profit. So they are left off!!

WAY FORWARD

1. Public sector drug companies IDPL,(Indian Drugs and Pharmaceuticals Limited http://www.medindia.net/buy_n_sell/pharm_industry/ph_hal.htm), HAL (Hindustan Antibiotic Limited http://chemicals.nic.in/pharma_idpl.htm) and other public sector drug companies should come forward to manufacture Essential Drugs.
2. When a drug company agrees to manufacture and supply certain groups of drugs, the company should also be compelled to take up the manufacture and supply of these essential drugs. The profit making drug companies owe the society at least this much.
3. Above all the people need to bring pressure on the politicians, bureaucrats and the government – as access to essential medicine is part of the people’s right to health.

• A summery of the discussion on 18th July 2006, with Dr H Sudarshan, former Chairman, Task Force on Health & Family Welfare and Vigilance Director, Karnataka Lokayuktha.

11. A STUDY TO DETERMINE THE MARKET SHARE OF ANTIANAEMIC DRUGS

As a part of this study a sample survey was conducted to;
   a. assess the volume of sales of drugs to treat anaemia and
   b. find out the most economic and the most expensive preparations prescribed.

Six retail chemists were identified in Ranebennur (a taluka place of Haveri district in Karnataka State, South India). They were requested to provide the figures of the total sales of iron containing preparations during a two month period from December 2005 to February 2006. A list of all the iron containing preparations sold by the retail chemists along with the corresponding bill amounts were provided to DAF-K for analysis.

Observations:
   i. The monthly sale of iron preparations at various chemist outlets ranged from 3.5% to 10% of the total sale of all the medicines.
ii. The sale of antianaemic medicines was more in those chemist shops located in the vicinity where gynaecologists practiced rather than in other outlets and generally indicated predominance of anaemia among women.

iii. The sale figures indicate that amongst the tablet/capsule category, the most economical one was priced at Rupees 0.90 or 90 Paise per tablet (HAEMUP GEMS). Closest to this, was priced at Rupees 1.20 per tablet (LIVOGEN CAPSULE TABLET), while the costliest was priced at Rupees 5.80 per capsule (SUPERACTIVE). Most other expensive brands were in the range of Rupees 3 to 4.50 per tablet/capsule. In the Syrup category, the costliest was priced at Rupees 85 per bottle of 200ml (OROFER). Next in range were for Rupees 60-70 per bottle of 200/ 300 ml. The cheapest sold was priced at Rupees 40 for 200 ml bottle (MIMIORANGE). The total sale of syrups constituted a range of 30% to 50% of total iron preparations sold.

iv. The drugs that were sold were all branded ones. None of the drugs at the chemist shop outlets were sold in generic form.

Chart 11.1 The total sales of all drugs and the sale of haematinics in 6 chemists outlets in Ranebennur (in Karnataka state)
for a period of two months.

<table>
<thead>
<tr>
<th>Chemist</th>
<th>Month and year</th>
<th>Total sale of all the drugs (Rupees)</th>
<th>Sale of only Haematinic (Rupees)</th>
<th>% of total sale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outlet 1</td>
<td>January, 2006</td>
<td>97,750</td>
<td>7331</td>
<td>7.50</td>
</tr>
<tr>
<td></td>
<td>February, 2006</td>
<td>97,500</td>
<td>7290</td>
<td>7.48</td>
</tr>
<tr>
<td>Outlet 2</td>
<td>January, 2006</td>
<td>104,000</td>
<td>5674</td>
<td>5.46</td>
</tr>
<tr>
<td></td>
<td>February, 2006</td>
<td>98,100</td>
<td>4642</td>
<td>4.74</td>
</tr>
<tr>
<td>Outlet 3</td>
<td>January, 2006</td>
<td>121,000</td>
<td>5272</td>
<td>4.36</td>
</tr>
<tr>
<td></td>
<td>February, 2006</td>
<td>118,200</td>
<td>4170</td>
<td>3.53</td>
</tr>
<tr>
<td>Outlet 4</td>
<td>January, 2006</td>
<td>103,878</td>
<td>10338</td>
<td>9.95</td>
</tr>
<tr>
<td></td>
<td>February, 2006</td>
<td>96,766</td>
<td>8077</td>
<td>8.35</td>
</tr>
<tr>
<td>Outlet 5</td>
<td>January, 2006</td>
<td>214,600</td>
<td>11160</td>
<td>5.20</td>
</tr>
<tr>
<td></td>
<td>February, 2006</td>
<td>204,200</td>
<td>9765</td>
<td>4.80</td>
</tr>
<tr>
<td>Outlet 6</td>
<td>December 2005 &amp; January 2006</td>
<td>294,000</td>
<td>12040</td>
<td>4.10</td>
</tr>
<tr>
<td>TOTAL SALE FOR TWO MONTHS FROM SIX OUTLETS</td>
<td>15,49,994</td>
<td>85,759</td>
<td>5.53</td>
<td></td>
</tr>
</tbody>
</table>

There are nearly 13,500 chemists and druggists outlets throughout Karnataka, as ascertained from Karnataka State Chemists & Druggists Association. It is projected from the above limited data that there is a total drug sale of around Rupees 1.74 billion* per month that includes the sale of haematinic preparations of around Rupees 96.5* million per month through 13,500 outlets as mentioned. (While this part of the calculation has a drawback in that only a limited number of six chemists outlets have been taken to project the sale of medicines for the entire State of Karnataka of 13,500 chemists...
outlets, and thus may not be epidemiologically accepted, these values are helpful to
give the reader an idea of the expenditure on medicines and more importantly on
the need for further studies).

**REQUIREMENT OF ANTIANAEMIC DRUGS FOR KARNATAKA AND INDIA – A PROJECTION**

In a projection, we have tried to look at the relevant costs of treatment for
nutritional anaemia with rational drugs for a period of 30 days in the state of Karnataka
and India.

At the rate of Rupees 11.70 per patient for 50% of Karnataka’s population of 20
million the cost of treatment for 30 days would be

\[ \text{Rupees 11.70} \times 20 \text{ million} = \text{Rupees 234 million.} \]

Projecting this to the population of India, which is around 1,000 million the cost of
treatment for 50% of the population is approximately

\[ \text{Rupees 11.70} \times 500 \text{ million} = \text{Rupees 5,850 million.} \]

As per the Government of India figures, the Indian drug manufacturers had a
turnover of Rupees 500,000 million during the year 2003-2004. The above estimates
show that we need approximately Rupees 5,850 million to treat 50% of the Indian
population of nearly 1,000 million for a treatment period of 30 days. This works out
to about 1.17 % of the total annual turnover of the Indian drug Industry.

<table>
<thead>
<tr>
<th></th>
<th>Rupees</th>
<th>Rupees</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grand total for two months</td>
<td>15,49,994</td>
<td>85,759</td>
</tr>
<tr>
<td>(as derived from chart 11.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>For one month</td>
<td>774997</td>
<td>428795</td>
</tr>
<tr>
<td>In one outlet for one month</td>
<td>129166</td>
<td>7146</td>
</tr>
<tr>
<td>In 13,500 chemists outlets</td>
<td>1,743,743</td>
<td>96,478,875</td>
</tr>
<tr>
<td>in Karnataka for one month</td>
<td>250 (1.74 billion)</td>
<td>(96.5 million)</td>
</tr>
</tbody>
</table>
12. CONCLUSIONS AND RECOMMENDATIONS

DAF-K arrived at the following conclusions and recommendations from the above study:

1. Only one of the listed medicines to treat anaemia is rational - ferrous fumarate, 200mg tablet, a generic drug, produced by a commercial manufacturer.
2. There are nearly a dozen preparations which are closer to a rational preparation only in terms of active ingredients but not their quantities or proportions. On this basis, all these preparations are also to be considered irrational preparations.
3. There is a third category of preparations which are indiscriminate combinations of several active ingredients that are not advised or recommended by studies. These preparations combine iron with a number of other supplements like vitamins, minerals, amino acids, proteins and other entities like liver extracts and create a situation which is complex by any consideration. This is ill-advised and not to be practiced. The cost of treatment through such combinations works out to be several times (from a minimum of 2 to more than 56 times) more expensive compared to the simple/generic medicines in this category.
4. Even the only listed rational antianaemia preparation, namely, ferrous fumarate is twice as expensive as the generic drug, a combination of ferrous sulphate 200mg and folic acid 1mg supplied by LOCOST, India/Supplies from CDMU/ Tamil Nadu Medical Services Corporation.
5. Rationality and price situation of drugs to treat anaemia, in spite of a verdict from the Supreme Court – the highest judicial body in this country - has remained a far cry from what it ought to be. (Public interest litigation (PIL) 693\1993 had been filed in the Supreme Court in 1993 to screen and weed out irrational and hazardous drugs by All India Drug Action Network (AIDAN), Drug Action Forum – Karnataka (DAF-K) and NCCDP (National Campaign Committee on Drug Policy), LOCOST and others. As a consequence to this court intervention several categories of therapeutic drugs have been weeded out. One such category namely antianaemic preparation in the Indian market were also examined by the court. The court specifically ordered weeding out preparations containing haemoglobin)
6. The government of India needs to intervene in the matter, first to make available rational preparations through commercial manufacturers and at the same time to totally curb the vastly prevalent tendency of commercial manufacturers flooding the market with irrational complex combinations. It is further necessary to prevent the gullible public from paying unnecessarily exorbitant prices towards preparations that are not warranted in any way.
7. The government should immediately weed out from the market all preparations that are irrational and harmful.
8. There should be an inbuilt mechanism so that a certain percentage of the turnout of the drug industry should be utilized for manufacturing such Essential Drugs as antianaemic medicines. After all, less than 1.17% of the total Indian drug industry annual turnover is needed to fulfill this requirement. However, this should not end
at just one drug category such as antianaemics but should also extend to most needed but NOT currently easily available drugs in the market.

9. The government should regulate the prices of drugs needed to treat anaemia and in addition all drugs should be price regulated.

10. The government should take stock of the drugs situation to treat anaemia and ensure that drugs are made available through public health systems.

11. The government should launch an education campaign and include topics related to better nutrition and anaemia in schools and colleges at all level.

12. People as their Right to Health should have access to food, water, education, shelter and sanitation

This study on drugs to treat anaemia has given rise to the above conclusions and recommendations which need to be circulated to various bodies interested so as to create awareness, to initiate basic actions towards change for the better for any real and meaningful completion of the project. The project took initiation from the correspondence that Drug Action Forum – Karnataka (DAF-K) had with Health Action International Asia-Pacific (HAIAP) 16.

13. RESPONSES FROM DRUG COMPANIES AND DOCTORS

DOCTORS’ RESPONSES
Drug Action Forum – Karnataka circulated a questionnaire among a few doctors to determine their attitudes towards prescribing antianaemics. (See annexure I for copy of the questionnaire). In total DAF-K received replies from nine doctors. Unfortunately the responses from doctors were not adequate and the number was not sufficient to reach a definitive conclusion. A summary of the findings from the answers given in response to the questionnaire from these doctors is given below:

1. Most doctors preferred to stick to a few brand preparations. This is in spite of the fact that the market is flooded with several preparations. Two doctors were prescribing four brands, while two doctors preferred to stick to only one brand.

2. Two of the doctors mentioned specifically that they had monitored the increase in haemoglobin after administering a specific brand. After having received satisfactory results they decided to stick to that particular brand.

3. Four doctors mentioned that the cost was an important factor in determining the brand name of the drug. And one doctor specifically mentioned that he/she preferred the tablet form of iron and folic acid, since the tablet form was cheaper than the capsule.

4. Four of the doctors mentioned that they preferred the capsule to treat anaemia on the ground that it was well tolerated and because it contained more nutrients.

5. Two of the doctors mentioned that they preferred a particular drug because it was from a ‘standard drug manufacturing company’.
Industry promotion – in the form of direct-mail brochures, journal, displays, professional courtesies or detail person or pharmaceutical representatives – is intended to be persuasive rather than educational.

The pharmaceutical industry cannot, should not, and indeed does not purport to be responsible for the education of physicians in the use of drugs.

Goodman & Gilman’s. The Pharmaceutical basis of therapeutics. 10th edition. Page number 64

DRUG COMPANIES RESPONSES: -

DAF-K wrote letters to four selected drug companies, for five products, inquiring the reason for manufacturing products which are irrational. The drug companies and their products in question are given below.

**Table 13.1 List of drug companies (along with the product and their contents in question) contacted by DAF-K**

<table>
<thead>
<tr>
<th>NAME OF DRUG COMPANY</th>
<th>TRADE NAME</th>
<th>CONTENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Franco Indian Pharmaceuticals Ltd,</td>
<td>Capsule Dexorange</td>
<td>Ferric ammonium citrate 160 mg, cyanocobalamine 7.5 mcg, zinc sulphate monohydrate 20.61mg equivalent to 7.5 mg, folic acid 0.5 mg.</td>
</tr>
<tr>
<td>Wyeth Ltd,</td>
<td>Capsule Autrin</td>
<td>Ferrous fumarate 300mg (98.6 mg iron), Folic acid 1.5 mg, Vitamin B12 15mcg</td>
</tr>
<tr>
<td>GlaxoSmithkline Ltd,</td>
<td>Spansule Fefol</td>
<td>Ferrous sulphate 150 mg, folic acid 0.5mg</td>
</tr>
<tr>
<td>Cipla Ltd,</td>
<td>Tablet Ferricip</td>
<td>Iron 50mg, folic acid 350 mcg</td>
</tr>
<tr>
<td>Cipla Ltd,</td>
<td>Capsule Cofol</td>
<td>Ferrous sulphate (time release form) 150mg, folic acid 0.5mg</td>
</tr>
</tbody>
</table>

DAF-K’s letter gave a brief introduction about the study and questioned the necessity for such contents and dosage form. Only two companies responded to our request letter. The gist of the correspondence is as follows:-

a. DAF-K’s correspondence with Franco Indian Pharmaceuticals Ltd: - DAF-K enquired as to why the company product contains ferric ammonium citrate with less than the recommended dose when ferrous sulphate was advocated both by the WHO and standard text books. Secondly DAF-K sought justification for the product being in capsule form. The company responded that “all ferrous salts are absorbed approximately to the same extent”. Consequently DAF-K wrote to the company again to enquire as to why ferric was used in the preparation instead of the recommended ferrous salt. The company had not yet clarified this point, before this report was sent to the press. As justification for the less than advocated dose the company replied that it was only meant for “prophylaxis and mild nutritional anaemia”. But the company failed to explain as to why the same
information has not been mentioned in its literature. Regarding the sale of the drug in capsule form, the company explained that “Dexorange capsule is an immediate release soft gelatin and not a delayed release capsule. Hence its disintegration is the same as the coating of a tablet”. DAF-K replied back that in spite of being gelatin, it did not offer any advantage over tablet form, but on the contrary increases the cost. Subsequently the drug company Franco Indian Pharmaceuticals Ltd, did accept that the cost of the drug increases!

b. DAF-K correspondence with Wyeth Ltd for its product Capsule Autrin: - The company explained that “all these ingredients assist haemopoiesis”. This is an explanation that DAF-K failed to clarify in any of the standard text books. The combinations that are present in Autrin are not rational and so do not find a place in any text books, because it is a combination of vitamin B 12, vitamin C, folic acid and ferrous fumarate. And as stated earlier combining iron preparation along with vitamin C and vitamin B 12 is not justifiable.

From this limited experience DAF-K learnt that: -

- Drug companies have misused and abused scientific information.
- There are no independent and unbiased authorities to question the drug companies.
- There needs to be an independent body which will both bring the regulatory authorities and drug companies to observe these important issues. Civil society has an important role to play in this process.
- Drug companies prefer to manufacture unnecessary and fanciful preparations with the aim of increasing drug costs.
14. SOME INTERESTING OBSERVATIONS

A. Out of the total 338 formulations that have been screened following are some interesting observations:-

1) 30% contained 1 to 2 ingredients; the rest (70%) contained more than 2 ingredients, making them outright irrational and a huge economic waste. This does NOT however mean that the 30% are all rational. Not at all!

2) 118 (34%) are in capsule form. “Since, iron usually is absorbed in the upper small intestine, certain delayed-release preparations, claiming to be even more effective when taken with meals than ferrous sulphate, are considered questionable”. Please refer page number 10 of this booklet for more details.

3) Vitamin B-12 is present in 153 (45%) formulations. “Vitamin B-12 has an undeserved reputation as a health tonic and has been used for a number of diverse disease states”. Please refer page number 11 of this booklet for more details.

4) Vitamin C is present in 55 (16%) formulations. The presence of Vitamin C causes “increased uptake of iron which is associated with a significant increase in the incidence of side effects”. Please refer page 10 of this booklet for details.

5) Zinc is present in 96 (28%) formulations. Zinc salts are known to decrease absorption of iron and thus aggravate anaemia.

6) Haemoglobin is present in 4 formulations.

7) Liver extract is present in 2 formulations. Government notifications have banned combinations containing Liver extract.

8) Alcohol is present in 7 formulations. Obviously there can be no justification, what so ever for the presence of alcohol, while treating anaemia!

9) HAEMOGLOBIN, LIVER EXTRACT AND ALCOHOL (THREE INGREDIENTS MENTIONED ABOVE) DO NOT FIND MENTION IN ANY TEXT BOOK OF MEDICINE!

10) Drug manufacturer Ranbaxy’s RICONIA ®, contains 33 ingredients. One wonders as to how the company could think of such a wide variety of substances. The contents of this drug would make one wonder as to how a doctor prescribing it ever remembers all these contents!

B. Injections are also used by practitioners to treat anemia and work out to be considerably expensive. For example anaemia treated by intramuscular injection, EFECIENT, costs Rupees 50 per ml. (5 ml ampoule Rupees 250) and cost of treatment for thirty days could be Rupees 4,500. (Calculated for 3 ml per day dosage).

C. Quotes from “Impoverishing the poor: Pharmaceuticals and Drug Pricing in India”, LOCOST/JSS, Vadodara/Bilaspur, December 2004

“Companies market iron salts in combination with a bewildering number of constituents like vitamins, minerals, aminoacids, trace elements, haemoglobin from slaughter houses (was a popular and completely irrational constituent of preparations till its ban in 2000),
stomach and liver extract just to increase the price of the preparation and to confuse the prescriber and the consumer without in any way adding to the therapeutic value”.

“The irrationality of the preparations tremendously increases the cost of therapy. The most glaring example of this is that of the best selling iron preparation Dexorange (Franco-Indian). It is an unnecessary syrup based preparation, which is inappropriate for adults. It contains an iron salt in a ferric form which has an inferior rate of absorption compared to the ferrous form. Till 2000 this preparation also contained haemoglobin obtained from slaughter house blood, which was totally unnecessary, irrational and possibly hazardous”.

“The government has done precious little to protect the health and the interests of patients and consumers. There is continued irrationality in the content of iron preparations and lack of any rationale in their pricing which is detrimental to the health of thousands of patients suffering from anaemia”.

“It was only due to the persistent efforts of drug action groups that the government belatedly banned the use of haemoglobin in iron preparations”. 14
An outstanding example of a patently irrational drug is Dexorange. This formulation is used for the treatment of one of the most common and serious health problems of people, anaemia. It is the top selling preparation with a Moving Annual Total in retail sales of Rupees 570 million. Its overall rank in the top 300 brands is No `16 and it outperforms some of the rational preparations for treating anaemia which do not even figure in the top 300 brands. Till 2000, this company for over a decade and half was adding a minute amount of haemoglobin obtained from slaughterhouses under unhygienic conditions to its otherwise formulation of iron.

The amount of haemoglobin added to the preparation was such as to provide an additional meager 2 to 3 mg of iron per 15 ml.

The addition of haemoglobin of animal origin to an iron preparation is without parallel in the pharmaceutical sector worldwide. No other formulary mentions it, and no other country allows it. How was this preparation passed for marketing in India? The answer is not clear. But it took years for the drug industry regulatory authorities to notice the irrationality of this top selling preparation and declare a ban on haemoglobin preparation and write:

“haemoglobin obtained from animal blood could be unhygienic and such preparations are needed to be taken in extraordinary high volume to deliver the recommended level of iron in anaemic cases and thus lacks therapeutic rationale”

This particular formulation still contains an iron salt, which is less efficiently absorbed, in a concentration that is low, and is still marketed at a price that is extravagant. The cost of treating iron deficiency anaemia with this preparation can be up to Rupees 600 per month, against the cost of a simple iron–folic acid preparation that should cost Rupees 9 per month.

The case of the consistent marketing success of Dexorange is not a mere example but stands as an eloquent testimony to the state of affairs in the pharmaceutical sector, the government and the prescriber, which has put the interests of the voiceless patient/consumer to the background. If after more than a decade during which this company marketed this top selling preparation adding animal haemoglobin from slaughterhouse blood, the government finds that this addition was not justified, and in fact hazardous, why did it allow a preparation like this to be marketed in the first place? Are the drug regulatory authorities so deficient in scientific understanding that they cannot evaluate a simple preparation for anaemia?
15. REFERENCES

3. Indian Medical Association’s Movement against Anaemia – ANAEMIA FREE INDIA. www.imanational.com
6. Why should iron – polymaltose formulations not be used? BODHI, Volume 8, number 1, March – April, 2001, page number 31 and 32. Taken from the source Indian Journal of Medical Sciences, Prof B C Mehta, Volume 55, Number 3, page number 157-158, March 2001
16) LETTER TO THE MINISTER

Date
To,
Minister of Chemicals & Petrochemicals,
12, Janpath, New Delhi - 110 001
Telephone number 011-23386519, 011-23386364
Fax number 011-23384020
mincf.cpc@sb.nic.in

Dear Shri

Re: Drugs available for the treatment of anaemia

We are writing with regard to drugs that are available for the treatment of anaemia in India. According to a study done by Drug Action Forum – Karnataka, there are hardly any rational drugs to treat nutritional anaemia in the country. It is extremely surprising and shocking to note that most commonly needed drugs are not available. According to the Delhi Gynaecologists Forum, India loses more than 2 billion dollars per year due to the loss of man hours and productivity resulting from 100,000 maternal deaths per year due to complications of pregnancy and childbirth. Anaemia is responsible for 40% of these deaths. It is also to be noted that over 90% of adolescents in Delhi are anaemic. The Annual Report MOHFW (Ministry of Health & Family Welfare) 2002-03 says only 35% of pregnant mothers receive prophylaxis against nutritional anaemia.

It is very unfortunate that rational drugs are not easily available to treat anaemia. Instead the market is flooded with several useless and irrational drugs. All these are a mere economic burden on the suffering patients who require economically priced drugs. The reason, drug companies are NOT interested in making drugs to treat anaemia, is because the industry does not make voluminous profits from simple rational compositions for antianaemia. Knowing fully well that the drug industry is a profitable one, we strongly urge you to correct this imbalance by taking the following measures:

- The Government should immediately weed out all preparations that are irrational and harmful from the market.
- There should be an inbuilt mechanism so that a certain percentage of the profit of the drug industry should be utilized for manufacturing such Essential Drugs that are most needed but currently NOT easily available in the market.
- Government should regulate the prices of drugs needed to treat anaemia and in addition all drugs should be price regulated.
- Government should take stock of the drug situation to treat anaemia and ensure availability of drugs through public health systems.
Government should launch an education campaign and include topics related to better nutrition and anaemia in schools and colleges at all level.

We hope you will look into this URGENT matter as it influences not only the health of a few, but the economy of our country too.

Yours Truly,

From

Copy to Drug Action Forum – Karnataka, 57, Tejaswinagar, Dharwad 580 002
GLOSSARY

Currency equivalent
1 US$ equals Rupees 46.51,
1 Indian Rupees equals 0.021 US$

Institutional Identities and acronyms

AIDAN All India Drug Action Network. A network of Indian non governmental organisations campaigning for rational drug and policies for more than two decades.

CDMU Community Development Medicinal Unit. A non governmental organisation for rational drugs. www.cdmubengal.org

CIMS Current Index of Medical Specialities. A commercial publication used by doctors in India for drug information.


FDA Food & Drug Administration. The US drugs and other consumer goods safety and efficacy recommending authority. www.fda.gov

HAIAP Health Action International Asia-Pacific. The Asia-Pacific arm of Health Action International an independent, global network working to increase access to essential medicines and improve their rational use.

HAL Hindustan Antibiotics Ltd. Indian public sector drug company.

IDPL Indian Drugs and Pharmaceutical Ltd. Indian public sector drug company.

JSA Jana Swasthya Abhiyan.

LOCOST Locost Standard Therapeutics. An Indian non governmental organisation involved in manufacturing and campaigning for rational drugs.

NCCDP National Campaign Committee on Drug Policy. A campaign group for rational drugs.

NEEDS Navodaya Environment & Education Society. A non governmental organisation for rural development through health, education and environment in Haveri taluk of Karnataka.


NSS National Sample Survey. A socioeconomic population survey undertaken by the government of India covering the entire country.

PIL Public Interest Litigation. A legal system (perhaps unique to India), wherein a person not affected by the problem can still challenge an issue in the court for public cause.

PHM People’s Health Movement. A global network of groups campaigning for health for all and health as a human right.

RCH Reproductive & Child Health. A government of India national health programme.

WHO World Health Organisation.
Drug Action Forum – Karnataka (DAF-K) is an independent, non-profit and non-governamental organization campaigning for rational drug therapy and policies. For its activities it depends on the voluntary donation from like minded individuals and organizations.

Other publications of Drug Action Forum – Karnataka :-
“Hepatitis B vaccine – Misleading Policy and Promotion” by Dr Gopal Dabade. A Kannada version on the same topic by Ms Sharada Gopal & Dr S L Pawar is also available. The booklet critically appraises the policies of the government of India on the issue of vaccinating every new born child with hepatitis B vaccine. Do we have enough resources for the same? Is it a priority disease in India? What are the alternatives? Additionally the booklet informs the reader about the correspondences that Drug Action Forum – Karnataka had with drug companies and the Drug Controller of India on this issue.

The English booklet is priced at Rupees 10/00 (postage extra). The Kannada booklet is priced at Rupees 5/00. For copies contact DAF-K at the address mentioned in the booklet.
Main findings of the study

- Anaemia is an extremely common problem and a major public health problem in several developing countries including India. In India more than 50% of the population is affected with anaemia and in several population sub-groups such as adolescents as high as 95% are suffering from it. Anaemia particularly strikes women and children. As per the Essential Drugs List of India and the World Health Organisation, the drugs needed to treat anaemia are a combination of iron with folic acid or a single iron preparation in correct doses. Internationally renowned standard text books of medicine have also advocated the same.

- After screening 338 drugs to treat anaemia from a popular doctors’ reference drug guide book (CIMS-Current Index of Medical Specialities Oct 2005-Jan 2006), it revealed that there is just one drug that fits into the standards prescribed by the Essential Drugs Lists of India and the World Health Organisation (WHO). Many of the drugs listed, to treat anaemia; in the doctors’ popular publication contained substances never advocated in any standard text books of medicine. Some even contained alcohol, liver extract and haemoglobin! The one drug that does fit into the standards prescribed by the WHO is NOT easily available at most chemists’ outlets, for the simple reason that it does not offer much margin of profit.

- The study observed that the cost of medicines to treat anaemia ranges from Rupees 0.13 per tablet to Rupees 6.97 per tablet, which works out to be as low as Rupees 11.70 to as much as Rupees 660 for a treatment period of 30 days. It was also observed that anaemia patients spend anywhere from a minimum of 2 to 56 times more than what they ought to.

- Even though the Indian drug industry has become a major global power in drug production it has not grown to meet the needs of this country, hence a vast majority of the population does not have access to essential medicines. This situation holds good for drugs to treat anaemia as well. As per the Government of India figures, the Indian drug manufacturers had a turnover of Rupees 500,000 million during the year 2003-2004. The above estimates show that we need approximately Rupees 5,850 million to treat 50% of the Indian population of nearly 1,000 million for a treatment period of 30 days with antianaemia medicines. This works out to about 1.17 % of the total annual turnover of the Indian drug Industry.

- **THE ENTIRE NATION IS FACING A SEVERE SHORTAGE OF DRUGS TO TREAT ANAEMIA – EVEN AT THE GOVERNMENT OUTLETS. THIS IS AN UTTER FAILURE IN MANAGEMENT AND LOGISTICS BY BOTH STATE AND CENTRAL GOVERNMENTS. A MATTER OF SHAME! A BIG SCANDAL!!** This is true even when there have been adequate resources available at all levels – state, national and international.
There are nearly 13,500 chemists and druggists outlets throughout Karnataka state. It is projected from limited data that there is a total drug sale of around Rupees 1.74 billion per month that includes the sale of haematinic preparations of around Rupees 96.5 million per month in Karnataka State alone.

In spite of the plethora of drugs in the market our limited study observed that most doctors preferred to stick to a few brand preparations.

In our correspondence with drug manufacturers we observed that drug companies have misused and abused scientific information, so that they could sell unnecessary and fanciful preparations at a higher price.

FROM ALL THESE OBSERVATIONS WE STRONGLY FEEL THAT THIS IS AN IMPORTANT AND URGENT ISSUE FOR ALL GROUPS FIGHTING FOR HUMAN RIGHTS AND ACCESS TO ESSENTIAL MEDICINES.

Join DAF-K’s call for action. Contact DAF-K at

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