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FUTURE TRENDS IN INDUSTRIAL APPLICATIONS OF MICROBIOLOGY IN PHARMACEUTICAL INDUSTRY*

by

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The scope of this paper covers the following aspects:

1. The population in Latin America and its probable development

2. The current situation regarding medical supplies and considerations on the future development in Latin America

3. An appraisal of the antibiotics in use today - in quantitative and qualitative terms - and probable developments

4. Considerations on the production of antibiotics in general and on the Latin American continent, in terms of the present situation and probable developments

5. Basic considerations on the production of antibiotics in the future,

   a) from a technical point of view

   b) from the patentees' point of view with regard to the production of antibiotics, the special prerequisites necessary for their production and processes

   c) from other aspects (in particular with reference to the question of training skilled specialists)

1. Let us look first of all at the population situation

In the light of diverse information available to us it may be established to begin with that:

In the year 2000 there will probably be twice as many people in Latin America as there are today, i.e. roughly 600 million. Latin America still shows the world's highest growth rates[+] While accounting for 8.5% of world population today, by then its share will be about 10%!

At the turn of the millennium the two most populous countries, Brazil and Mexico, with about 350 million, will continue to account for over half the population of Latin America, and here the trend will be upward.

I may add by the way that in Brazil the average life expectancy is already 63.6 years today, in Mexico 65.4 years, while Cuba, our host country, today records the highest life expectancy at 71.8 years.

[+] (1978 Centro latinamericano de Demografia - CELADE in Santiago, which operates on the basis of an agreement between Chile and the UN).

SLIDE: The Population of Latin America

The Population of Latin America

(in millions)

	1960	1975	1978	1985	2000	Annual Growth in %
Latin America....	207.8	312.8	339.2	409.8	597.2	
Andean Zone.....	48.3	73.9	79.9	96.0	136.4	
Bolivia.....	3.3	4.8	5.2	6.3	9.2	2.63
Colombia.....	15.7	23.8	25.6	30.4	42.4	2.44
Chile.....	7.5	10.1	10.7	12.0	14.9	1.72
Ecuador.....	4.4	6.5	7.5	9.3	14.5	3.08
Peru.....	10.1	15.4	16.[illegible]	20.3	29.4	2.79
Venezuela.....	7.6	12.6	13.9	17.4	15.7	3.34
Atlantic states....	96.4	140.6	151.6	169.3	254.0	
Argentina.....	20.6	25.3	26.3	29.6	32.3	1.29
Brazil.....	71.5	109.7	119.1	145.0	212.5	2.86
Paraguay.....	1.7	2.6	2.8	3.5	5.2	2.95
Uruguay.....	2.5	2.8	2.8	3.0	3.4	0.56
Central America..	12.2	19.4	21.2	26.2	40.1	
Costa Rica.....	1.2	1.9	2.1	2.4	3.3	2.41
El Salvador.....	2.5	4.1	4.5	5.5	8.7	2.97
Guatemala.....	3.9	6.2	6.8	8.4	12.7	3.07
Honduras.....	1.9	3.0	3.5	4.3	6.9	3.59
Nicaragua.....	1.4	2.3	2.5	3.2	5.1	3.34
Panama.....	1.0	1.0	1.8	2.2	3.2	2.32
Mexico, Caribbean.	50.2	78.8	86.3	107.2	166.5	
Cuba.....	7.0	9.3	9.7	10.6	12.7	1.33
Haiti.....	3.7	5.1	5.5	6.5	9.8	2.40
Mexico.....	36.3	59.2	65.4	82.8	132.2	3.39
Domin.Rep.....	3.1	5.1	5.6	7.1	11.7	3.41

In rough figures it can be said that the total population of Latin America in

1960 was about 208 million

1975 about 313 million

1978 about 339 million

It is estimated for

1985 at 410 million

2000 at 597 = approx. 600 million.

It is also interesting to note the change in the ratio of urban to rural population. While in 1960 the ratio was still about 1 : 1, in 1975 it was already about 3 : 2, similar to the situation in industrialised countries.

It is likely that the dramatic growth in the proportion of urban population in a few parts of Latin America will continue to expand.

It is obvious against this background that the concern for the creation of new jobs and the development of appropriate industries is thus of prime importance, as reflected in the demand for 25% of worldwide production capacities in the developing countries in the year 2000.

2. The situation regarding current medical supplies and considerations on future developments

Although virtually all countries of Latin America still feature among the " developing countries " in UN surveys, it must be observed, in the light of all the statistical material available to us, that in a large majority of the countries, the medical supply service for the population has already reached a notably high standard.

I may, for instance, quote figures that are known to me for at least a few countries

Argentina		100%
Brazil	close on	90%
Chile		95%
Colombia		70%
Cuba		100%
Mexico		85%
Venezuela		100%

All countries provide in part highly effective medical facilities which, in some cases, are also deliberately oriented to still marginal sections of the population, such as the medical supply service for the " poblacion indígena " of the " Instituto Nacional Indigenista de México".

While in many developing countries in Africa and Asia there are special logistical problems in the distribution of medical supplies, as far as Latin America is concerned, it may be said that, today, this only poses

a certain problem in very few extremely remote regions of Latin America.

The development may be best illustrated perhaps with the example of Brazil, where 10 - 15 years ago remote parts of the country could only be supplied by plane or after correspondingly long delivery times; most pharmaceutical concerns had to maintain various depots distributed through the country. Today most manufacturers deliver from the factory by truck, it now only taking a few days to reach even the remotest areas!

The efforts, partly of state insurance institutions, partly of the Health Ministries - and not least of all as a result of the introduction of a practical year for young doctors in the interior of the country - have given rise to a widespread medical service.

You will no doubt agree that certain factors of uncertainty can be in these statistical statements, so we should try, by drawing on further data, to arrive at a few clear facts.

With a population today of about 350 million, Latin America makes up 8.5% of the world's estimated current population of about 4,125 million.

If we take a look at the figures we have for total sales of pharmaceuticals, we shall see that Latin America's share is about US$ 3,600 million in value terms and about 7.5% in percentage terms, though admittedly given an, in part, lower price level. According to other sources 9% market share of the western countries' world market.

The difference between this 7.5% market share and the 8.5% share of world population does not appear over large. We must therefore draw on other comparative figures.

Let us take the figures we have on per capita consumption, as one of the most informative statistics. (We have these in D-Mark).

SLIDE. Per capita consumption of pharmaceuticals in DM

Per capita consumption of pharmaceuticals in DM

North and Central America

Mexico	18.47
Central America	18.54

South America

Brazil	25.05
Argentina	50.89
Venezuela	58.09
Colombia	22.16
Peru	21.01
Chile	26.12
Ecuador	16.42

You will notice quite substantial differences, from just over DM 10.-- to DM 58.-- (figures for 1977).

Let us disregard the price differences in the countries. They have also led to considerable debate in Europe, too, and we have come to the conclusion again and again that a different price level can very often be the reflection of different cost structures in the countries. If we therefore take these figures as guide values, we find that the differences ultimately show how divergent the actual supply of pharmaceuticals still is in these countries.

Still, in this connection, it is noteworthy that Venezuela - as the richest oil producer so far on this continent - has reached a per capita consumption of DM 58.--.

It will surprise you that a country such as Canada only registers close on DM 61.--.

The figure for the USA, on the other hand, is just short of 100.--, while for Switzerland, Belgium, France and West Germany per capita consumption was between about DM 130.-- and DM 145.--.

Let me just mention another point:

While per capita consumption in the Federal Republic of Germany was DM 143.--, in the states of the Eastern Bloc it is:

GDR	DM 100.--
Czechoslovakia	DM 81.--

This relationship leads us to the conviction that the consumption of pharmaceuticals utlimately depends on a country's level of industrialisation. In other words: the more advanced a country's industrial development, the higher the consumption of pharmaceuticals.

Before leaving these considerations let me just refer to the countries with the lowest per capita consumption, which are all to be found in Africa and the Far East:

Sri Lanka	DM 2.44
Kenya	DM 3.43
India	DM 3.28
Pakistan	DM 3.63
Indonesia	DM 4.73

I quote these figures deliberately, for they are an interesting indication for Latin America of how far this continent has already advanced and ultimately point to where the real problems of the WHO objective ("Health for All by the Year 2000") lie.

While it is probable that in a large number of developing countries in the African and Asian regions up to 80% of the population are not adequately provided with health services and medical supplies, this situation is probably reversed, or perhaps even more favourable, in terms of the continent as a whole.

Let me quote the figures from the statements made at the UNIDO Symposium in New Delhi/Anand (20. - 30.11.1975) according to which the developed countries account for 85% of world production and 85% of world consumption of pharmaceutical products, which means that, if these figures are correct, the developing countries make up only 15%.

Let us now take the following figures:

1. The population of Latin America amounts to about 300 million in 1975.
2. For 260 million of the population, per capita consumption of pharmaceuticals is about DM 23.--.
3. For only 40 million (Argentina and Venezuela), that is 15% of the current population of Latin America, per capita consumption of pharmaceuticals ranges from approx. DM 50.-- to 60.--.
4. An increase in per capita consumption of the total population to the higher figure would, theoretically speaking, mean a doubling of the present consumption of pharmaceuticals.

5. The expected doubling of th population would mean a further doubling, that is, in all a quadrupling, of present consumption.

6. Moreover, if we consider the still highly divergent life expectancies, a further growth of at least 20% must also be assumed (given increase in average life expectancy from between about 55 and 65 years to over 70 years as, for instance, in Cuba), for it is an established fact that the consumption of pharmaceuticals is higher in advanced years, owing to a higher sickness index, than among younger people.

All this is a premise, but a premise we should hope will become reality in the interest of all, above all in the interest of the people living on this continent.

From these figures it can be concluded that, to rise from I 0 to 400 in 20 years, r ighly 7.5% more pharmaceuticals, and thus reagents an d process materials, and thus also antibiotics, will have to be made available.

3. Appraisal of the antibiotics in use today

We have at our disposal the following antibiotics of diverse derivation:

3.1 List of antibiotics by groups of substance and year of introduction:

See SLIDE

Products with unbroken underlining are based on fermentation
Products with broken underlining are based on fermentation and synthesis

(Chloramphenicol fully synthetic)

In addition, data on the year of introduction

Penicillins	
Penicillin G	1941
Penicillin V	1953
Methicillin	1960
Carbenicillin	1967
Ampicillin	1961
Amoxycillin	1974

Cephalosporins	
Cephalotin	1964
Cephaloridine	
Cephalexin	1969
Cefazolin	1973

Aminoglycosides	
Streptomycin	1944
Neomycin	1949
Gentamycin	1963
Tobramycin	1971

Tetracyclines	
Chlortetracycline	1948
Tetracycline	1953
Demethylchlor-tetracycline	1960
Doxycycline	1966

Other Antibiotics	
Fusidic Acid	1967
Lincomycin	1963
Cycloserine	1964
Polymyxin	1947
Trimethoprim	1968

Chloramphenicol	1947
Macrolides	1952
Erythromycin	1952

3.2 Market share of antibiotics

The full range of anti-infectants accounts worldwide for the largest share of the pharmaceuticals market. On the basis of producer prices the percentage share on the world market was approx. 17% in 1977 (SCRIP).

If this is looked at more closely, wide differences will be found with respect to national markets which certainly cannot be explained solely by different health conditions, but probably are also attributable to medical school opinions or to the specific attitude of the doctors.

Let me give a few examples:

See SLIDE : Consumption Worldwide of Antibiotics

Worldwide consumption of antibiotics	approx. 17%
Japan	approx. 23%
Spain	approx. 27%
UK	approx. 15%
FRG	approx. 9%
France	approx. 8%
Italy	approx. 11%
Argentina	approx. 16%
Brazil	approx. 18%
Colombia	approx. 18%
Peru	approx. 18%
Mexico	approx. 20% (in hospitals approx. 29%)

On the assumption that the market research statistics are based mainly on the chemist retail market and that hospitals - which are particularly important for antibiotics consumption - and distribution via state agencies (Centros and Puestos Medicos) are only partly included, an overall percentage of approx. 20% can be presumed for Latin America.

3.3 Market share of individual antibiotics

Subject to all reservations, I may quote a few figures for percentage market shares on the individual national markets of Latin America to the extent that such information is available to us.

See SLIDE:

1974/75

	Arg	Braz	Col	Peru	Mexico Pharm.	Mexico Hosp	Total Latin America
Tetracyclines	21	21	24	23	18	3	20
Chloramphenicoles	11	5	3	12	5	1	5
Ampicillines	20	23	29	17	26	35	30
Cephalosporines	7	4	4	2	6	13	5
Erythromycines	16	14	15	12	16	11	15
Penicillines	2	10	6	11	11	23	10
Others (Aminoglycosidos, Cotrimoxazol, Linomycin, etc.)	23	23	19	23	18	14	15

This table would suggest, so far as we feel we can rely on these figures, that consumption must be studied very closely from country to country to avoid drawing incorrect conclusions from possible reference to average figures (see Total Latin America).

At this point mention must also be made of the importance of antibiotics as an additive for animal fodder. While in countries with highly developed livestock farming the use of antibiotics is expected to yield increases of about 8 - 10% in meat production given the same amount of fodder, this percentage rises in countries with difficult hygiene conditions, inadequate medical services and poor fodderstuffs

to up to about 30%.

Formerly, the antibiotics used for human medicines and for animal fodder were identical.

Thus, up to 50% of worldwide production of Penicillin G was used for animal fodder (as late as 1969), while today the percentage is probably about 30% and is continuing to fall.

Today, growing use is made of specific antibiotics for animal fodder, such as Flavomycin and Monensin. It is decisive - and I wish to stress this here - that account also be taken of such requirements in industrial planning. Unfortunately, it is to be observed that even the large producers only have very general estimates of requirements, but no, even reasonably, reliable statistics from which serviceable figures can be derived!

3.4 Figures for worldwide production of Penicillin G and V (1975)

Region	Land	Total Tonnage
N. America	US	3,800-4,000
Latin America	Mexico Brazil Argentina	200- 300
W. Europe	UK	1,600-1,700
	Netherlands	800- 900
	France	200- 300
	Denmark	200- 300
	Germany	200- 250
	Austria	200- 300
	Spain/Portugal	500- 550
	Italy	450- 500
	Sweden	50- 100
	Total approx.	4,200-4,900
E. Europe, including:	Hungary Czechoslovakia Bulgaria Other countries	200- 300
Japan		600- 700
Rest of World		100- 200
Total (average)		9,700 =

Figures for production of semi-synthetic penicillins by region (1975)

(Tons)

	Semi-synthetic penicillins	-- Derived from (ton) -- Penicillin G and V	6-APA
W. Europe	1,750-1,950	2,700-3,000	1,350-1,500
US	500- 550	770- 850	385- 425
Japan and rest of world	200- 250	300- 383	150- 190
Total (say) +	2,450-2,750	3,800-4,200	1,900-2,100

+ Figures have been rounded, and therefore total figure may not be an exact sum of individual regional production.

The figures reproduced here are intended primarily to give a better knowledge of the background material worldwide.

3.5 Regarding the development of antibiotics in general the following observations may be made today:

1. The search for wide-band antibiotics with as low a tendency as possible towards resistance and a broad spectrum of action, not to mention the search for substances with less side-effects and effective therapeutic doses with smaller amounts will continue.

2. A few of the antibiotics used today will continue to occupy a preferred position in therapy in terms of quantity, such as the penicillins and semi-synthetic penicillins, ampicillin and amoxycyclin, tetracyclin, streptomycin, cephalosporine and derivatives similar to tetracyclin.

   This statement does not, however, take account of the development of resistance to these substances which cannot be excluded and which in turn necessitates the renewed search for other antibiotics.

3. For all antibiotics special importance will attach to the search for [illegible] selection techniques and the development of higher-yielding strains. In this connection, I would refer you to the survey " Genetics of Antibiotic Production " by HOPWOOD and MERRICK, published in September 1977 in Bacteriological Reviews, Vol. 41, No. 3.

Here it is observed, inter alia:

" Yet knowledge of the genetics of antibiotic production, and even of the biosynthetic pathways of antibiotics, is still disproportionately small. In part this arises from the fact that, aside from mutagenesis, which has been employed on a huge scale, genetic approaches to the improvement of strains for industrial antibiotic production have been largely ignored ".

4. Considerations on the production of antibiotics in general and on the Latin American continent; the situation today and probable development

It may be assumed, especially after Mr. Sittig's paper, that the basic problems are familiar. Let me therefore begin with a few general observations:

1. The production of pure fermentation antibiotics lends itself for the first stage of primary material production, for

a) in view of the required nutrients, the raw materials are available on the continent (especially sugar),

b) an appropriate range of refined chemicals is not required as for all chemical syntheses. But it must also be added here that UNIDO generally only recommends

the establishment of fermentation plants when a few other intermediate products are already manufactured from local raw materials. It was observed, for instance, at the UNIDO Meeting in India in November 78:

" The complete synthesis of pharmaceuticals from the lowest stage depends largely on the development of the chemical industry in the country concerned. Where the chemical industry is not yet sufficiently developed, it is practically impossible for the pharmaceutical industry to start synthesis from the very lowest stage".

2. A few basic, general problems must be considered today before embarking on planning of any kind:

Factors of importance for site selection.

For complete fermentation there is a high energy requirement (approx. 20% of production costs). Sufficient quantities of water are required, which - as mainly used as cooling water - must be continuously cooled to a temperature of less than 15^{o}.

A fermentation project in Northern Latin America could not be taken into production, for instance, as not enough water could be made available.

3. Referring back to what I said in Point 1, it must be added that the production of semi-synthetic antibiotics raises similar problems as for the synthesis of pharmaceutics in general. Success can thus only be expected if the corresponding conditions are fulfilled.

4. Certainly, a number of countries in Latin America already have first production capacities for antibiotics, partly for pure fermentation, but also probably for the production of semi-synthetic antibiotics.

Here, I can only give a general overview on the strength of information I have received from various sources:

See SLIDE: Production Capacities for Antibiotics in Latin America

Several international companies have established production capacities for antibiotics in

Argentina	Lilly, Pfizer, Squibb, Glaxo
Brazil	ditto, and Merck/USA
Colombia	Glaxo
Costa Rica	Pfizer (planned 1966), Merck USA
Ecuador	Merck/ USA
Guatemala	Lilly, Squibb
Mexico	Lilly, Merck/USA, Pfizer, Squibb, Glaxo, also Fermic S.A., which produces ampicillin, cefalexin, eritromycina, gentamicina, oyitetracilina, and tetraciclina. Several firms produce chloramphenicol.
Panama	Squibb
Peru	Merck/USA, Squibb
Venezuela	Merck/USA, Pfizer, Glaxo
el Salvador	Glaxo

The following substances are named:

Tetracyclin, doxycyclin, oxytetracyclin, chlorpropamid, amphotericin, streptomycin, micostatin, neomycin and penicillins.

Unfortunately, I am unable to quote any figures for production volume, as these are not known to me and, besides, are probably subject to constant change, especially as a number of the production capacities I named are presumably still in their infancy or are still in the process of being established.

FIFARMA in preparation for the UNIDO Conference of the " Primera Reunion de Consulta sobre la Industria Farmaceutica " in Cairo , moreover, already observed " that 14 of the 16 substances are already produced in various countries of Latin America ."
(This list included, inter alia, ampicilina, bencil penicilina, tetraciclina, fenoximetil penicilina, estreptomicina).

5. General Considerations on the Production of Antibiotics in the Future

a) From a technical point of view

1. General observations

We had already mentioned the special importance of improved strains for increasing production yields. Generally it can be said that production improvements lie to about 80% in improved strains and to about 20% in improved media.

Generally it may be said that productivity will be roughly doubled in 10 years, the percentage being higher in the case of new antibiotics owing to new strains than in the case of older substances where the improvement of strains has already reached a certain peak.

Of one leading European manufacturer of antibiotics I can say that in the case of its three major preparations it has, in the last 10 years, doubled the yield of one, quadrupled the yield of the next youngest and increased eightfold the yield of the most recent preparation.

Each new strain leads to a corresponding revision of the entire process.

2. Pure fermentation processes

Aside from the search for improved strains, the development in the field of nutrient media is probably moving towards chemically defined media, i.e. media which, providing an optimal "food supply", make for faster and more extensive fermentation, with a corresponding reduction of ballast matter.

Owing to the positive effects, the resulting increased cost of the media can be more than offset by the other advantages, especially as in the case of synthetic media with less ballast matter simpler plants can be used.

3. Synthetic processes

It is generally assumed that the search for purely synthetic production of antibiotics will not yield any further successes. Chloramphenicol will probably remain the exception owing to its simple construction.

Through the improvement of strains that I mentioned earlier and the possible improvement of media, such high yields are achieved today that pure synthesis, which would probably require 10 - 12 stages, is becoming prohibitive for cost reasons.

After all, today, the costs for bulk products are between DM 50.-- and DM 100.--, for sterile procainpenicillin about DM 60.-- and for oral tetracyclin between DM 60.-- and DM 70.--

The path of semi-synthesis will probably be further pursued; as to the considerations for setting up production in Latin America the required presence of an adequate chemical industry, as precondition, was discussed earlier.

In future, too, there is little likelihood of multiple-purpose plants being used for the production of semi-synthetic antibiotics, for general opinion is that, per synthesis, only one fixed plant guarantees production without complications of substances of the required high purity.

A further technical problem is that extremely low temperatures of up to minus 50°C are required for the synthesis of antibiotics, i.e. temperatures as required in only few cases for other types of synthesis. So here we are dealing with one of the more difficult organic syntheses.

It is already being practised to some extent, but efforts are also still being made to substitute chemical-synthetic stages with enzymatic synthesis in the future. This is being realised on a larger scale by splitting Penicillin G, and recently also Penicillin V, into 6 APA with enzymes, which are either isolated or fixed on plastic, or, originally, by using the enzyme-producing micro-organisms.

General information on future trends are to be found, as you know, in the studies of the Stanford Research Institute and in the publishings of Bernhard Wolnak, London.

4. Now let me just say a few words on the preparation of the fermentation product:

Here we are faced with the following problems:

a) Improvement of the separation of the mycel, in particular of the filtration process

b) Recycling of the mycel

c) Preparation without the use of solvents. The path away from solvents results from the desire to further reduce production costs by eliminating the solvents.

5. Other problems

A not insignificant side problem is the processing or utilisation of the mycel, which occurs in large quantities. All mycels lend themselves as ideal folderstuffs. However, the USA and West Germany have banned their use untreated, as they fear the encouragement of resistance and allergies.

This danger is exaggerated in the opinion of many experts. To reverse or amend the statutory regulations introduced is proving particularly difficult in the countries I mentioned. We can therefore only hope that others will learn from this.

Undoubtedly the use of mycel as fodder thus appears to be the best solution. A few countries have had excellent experience with the dumping of mycel in the sea, registering an outstanding development in shrimp and crayfish yields.

The USA has also banned this today, the British haven't!

The second-best alternative is dumping and composting, while the least favourable way is to prohibit the further use of mycel, even though today with the improved production yields the proportion of mycel is no longer as large as in the past.

5 b Patents situation

Let me first make one general observation on this point which is of such extreme importance for the industrial nations:

The development of the pharmaceutical industry depends largely on its expenditures for research and development. This expenditure is a vital part of its activities. It involves the search for new reagents, but also the continuous servicing of reagents already introduced in all its facets (production and process engineering, clinical-pharmacological innovation, improvement of analysis methods, and the constant supply of information to prescribing doctors on the one hand and to licensees on the other).

The protection of this know-how is of overriding importance for countries with few raw materials, such as, in particular, Germany and Switzerland.

Perhaps you will permit me to remark here that we are of the conviction that all major inventions of the pharmaceutical industry have been made in non-state enterprises and let me add, too, that the attitude to patent protection, to which I shall be reverting a little later, is subject to constant change.

In this connection, it is not without interest to note that the USSR, too, has become a party to the Paris Convention.

Now, how do we view the situation regarding patent protection in Latin America today?

See SLIDE:

Tabelle

Patent Protection for Pharmaceuticals in Selected Developing Co ntri es

PATENTE DE PROTECCIÓN DE PRODUCTOS FARMACÉUTICOS EN PAÍSES EN DESARROLLO SELECCIONADO

PAÍS	SITUACIÓN SATISFACTORIAS DE LA PATENTE	PATENTE LEGAL POSIBLE, PERO SIN VALIDEZ	PATENTES NO PERMITIDAS
AMÉRICA CENTRAL Y DEL SUR			
BRASIL			+
ARGENTINA		+	
CHILE		+	
VENEZUELA		+	
PERÚ		+	
ECUADOR			+
COLOMBIA		+	
PARAGUAY		+	
URUGUAY		+	
MÉXICO			+
COSTA RICA		+	

NATIONAL ACADEMY OF SCIENCES, INSTITUTE OF MEDICINE CONFERENCE ON PHARMACEUTICALS FOR DEVELLOPING COUNTRIES JANUARY 29-31-1979, WASHINGTON, D.C./ HEALTH, PHARMACEUTICAL AND DEVELOPMENT INDICATORS WORLD WIDE (IMS)

This survey illustrates that an effective patent protection no longer exists today.

However, patent protection is only one side of the problem. The other side is and will remain: with or without patent protection how can I gain access to the know-how that I require for optimal performance of a complex production process, and at the same time have the assurance that I will also participate in relevant innovations in the future.

At this point opinions differ and everyone naturally tries to defend his own position.

I may also refer to the UNIDO Conference in Dehli/ Anand in November 78:

" Even where a good process know-how is available, the next important factor for the success of any project is proper process engineering and design. "

The debate on the transfer of know-how is not made any easier, as, on the one hand, it is raised in many cases by states, the donors of the know-how, on the other hand, are however private business enterprises. The last UNCTAD Conference on technology transfer showed that the differences on major points are still irreconcileable.

(Text einzufügen : Deutsch Seite 25)
letzter Stand Vorbereitungen für nächste Konferenz)

The Neue Züriche Zeitung wrote on 15.11.73:

" Aside from the fact that one cannot expect western governments to oblige their private industry to surrender industrial know-how, that they intervene in a regulatory capacity in inter-company relations or that, in cases of arbitration, the national law of the recipient country be always applied, there are in the background also politically explosive issues. The western industrial countries are fully prepared to aid development by putting forward proposals for a transfer of technology to the countries of the South that is free from abuses. "

I should like to quote this one sentence from the UNIDO Conference in Delhi/Anand:

"Therefore, ideological considerations should not be allowed to stand in the way of availing of such technology and expertise from firms in developed countries ."

5. c) Other considerations

Special attention will have to be focussed on the appropriate training of skilled specialists for production, and here above all at works superintendant and foreman level. From my point of view I can naturally merely make the recommendation that, in addition to the regular supply of latest production know-how, sensible licence agreements must needs include an appropriate servicing of the production plant, and in particular also

the appropriate training and, where necessary, initially the supervision of local personnel who are to assume responsibility for the individual production stages.

Undoubtedly, in most countries of Latin America - though this depends on the level of development of the chemical-synthetic industry - there are already a large number of workers and skilled workers, such as foremen and superintendants, who are at least basically familiar with such production processes.

From my own experience I can only confirm that the worker and specialist in Latin America, given the appropriate experience, is no better and no worse than his counterpart from other countries, but that, perhaps because of his immediate experience of the beginnings of industrialisation and specialisation, he can be more resourceful and willing.

I may just mention, by way of example, the experiences of India:

For lack of adequate practical training capacities in industry, India's universities already started soon after the country's independence to create appropriate training capacities at the universities and technical colleges, which went so far as the planning and construction of complex pilot plants.

In a transition period it should be considered to send specialists at universities and other institutions to countries which offer training capacities for the required kind of work. In this connection, the exchange among the developing countries themselves, as planned by UNIDO, can be particularly valuable.

And a further word on " regional cooperation " :

As a theoretical stimulus this proposal naturally presentsan ideal solution for certain groups of countries to set up profitably operating production capacities. I cannot and do not wish to say more on this subject. Knowledge of this continent and the experiences with the various economic groupings from Alalc, Pactoandino to the " Common Market of Central America " with its regrettable disputes between Salvador and Honduras cannot dispel the scepticism, even of the greatest friend of this continent as a whole.

Penicillin-G-Potassium 1 mg = 1595 IE

Penicillin-G-Sodium 1 mg = 1670 IE

1 million IE = 1 MEGA-Ein = 0.627 gr Pen.-G-Potassium

1 bn = 1000 " " = 0.627 kg " " "

1000 bn = 1 million ME-E = 0.627 to " " "

1 M M U

= 1 TERA-U

World production 15423 MMU = 9,700 to " " "

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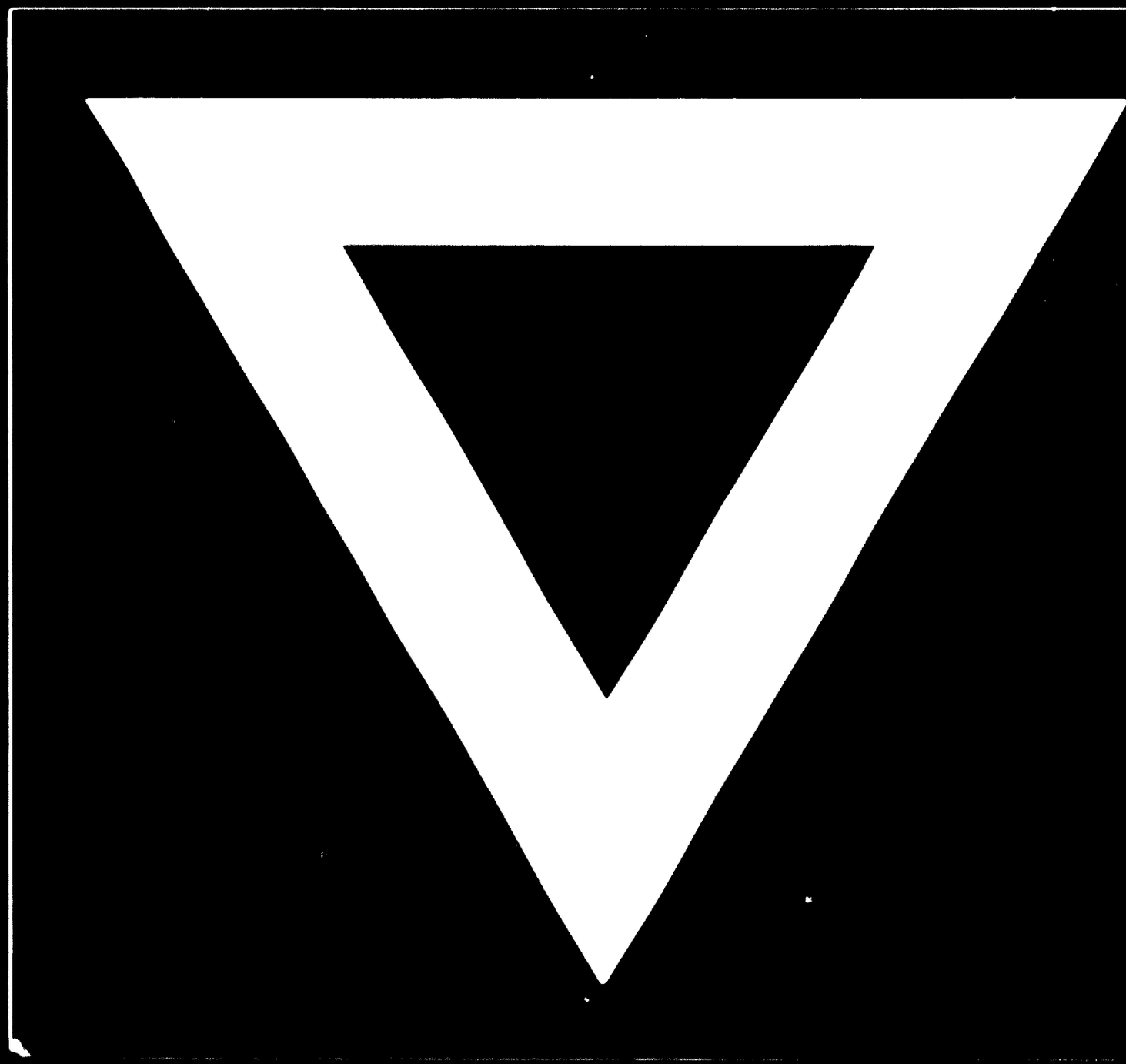

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