The Society is always looking for new members who will be prepared to devote a small amount of their time to attending the meetings of the Society which commence at 5 p.m. and last, as previously mentioned, for approximately one and a half hours.

The Society has a number of members who are either employed by or act for those Life Offices which have specialised in unit-linked business but this aspect of life assurance business has not, despite its general acceptance by the industry, provided a great deal of discussion at the Society's meetings.

Our penultimate lunchtime talk took place on Wednesday, 12th March, in Committee Room 2 of Aldermary House, the headquarters of the ABI. (The change of venue was necessary because the new ILU premises were not at that time available for us).

The large audience heard Mr. Klaus-Dieter Reinhold, a lawyer with the Munich Reinsurance Company, speak on

"The German Pharma Pool and its Experience"

As you surely know and as Mr. von Bechtolsheim (BILA Committee member - ed.) mentioned before, the development in Products Liability insurance and, specifically, Products Liability insurance for pharmaceuticals on international markets over the past two or three years has been catastrophic. Severe losses, often in the range of hundreds of millions of US$, the subsequent sharp reduction of insurance capacity on all markets, increasingly stringent conditions and premium increases characterize the situation. The fact that premium increases are often not only 100% but anywhere from 200, 300 to 500% is of some significance. At the same time brokers have often not been able to place this business even though the premiums increased so tremendously.

For these reasons it is, I hope, interesting to hear about the picture in Germany and how the Pharmapool handles these problems. It might be interesting too, because Germany is the third largest producer of pharmaceuticals in the world, after the USA and Japan and has the largest pharmaceutical export of all countries.

I would like to break down my explanation of the situation in Germany into three parts:

First, the Germany Pharmaceutical Act (Arzneimittelgesetz) and the foundation of the Pharmapool.

Second, the structure and function of the Pharmapool.

Third, experiences to date.

First of all, concerning the Pharmaceutical Act:

Many of you will remember that in the early 60's, the thalidomide catastrophe shocked all of Europe and many countries beyond. At that time thousands of children were born without arms or legs or were crippled in some way, hundreds died. The cause of this is said to have been the sedative thalidomide taken by expectant mothers. This case was one of the main motives for a fundamental revision of German drug laws. The result of this, which involved years of work and difficult negotiations with industries involved, scientists, politicians, the insurance industry etc., was the Pharmaceutical Act which came into force on 1st January 1978.

To concentrate on the more important points of that law, I would like to summarize the whole story in three parts:

First of all, extremely stringent regulations for the manufacture, development, sales and testing of drugs were set. The requirement to submit a new drug to a specific authority, the (federal) Department of Health in Berlin, for its explicit

authorisation before a drug is admitted onto the market, has replaced the simple registration requirement which was in force up to that time. The health authority has more power than ever to conduct continuous investigations and can also either withdraw a drug from the market or impose severe restrictions on its sale and distribution.

Through this measure, drug security, which in Germany has maintained a high standard over a long period of time, was once again considerably improved. The great sense of responsibility in the German industry has also played a major role here.

Second, this law which is designed to protect the consumer has introduced the strict liability of the pharmaceutical entrepreneur. According to Section 84, the pharmaceutical entrepreneur, that is, he who supplies a drug under his own name, is liable for any harmful side-effects of his products, if these side-effects exceed certain dimensions. This is to apply even where he is not guilty of negligence. Liability is limited to DM 200 m per drug, and I emphasize here the words "per drug". This means that a pharmaceutical entrepreneur who manufactures, say, 10 drugs is liable for up to DM 2 billion in damages, which is more than £500m.

Here it is especially important to note that liability also includes the so-called risk of development, which means that the pharaceutical entrepreneur also bears resonsibility for side-effects which have not yet become apparent at the time the product was first marketed, but only much later.

The third item of the law and the most important section for the insurer is a stipulation which is presumably unique in the world. It states that a single branch of the industry, which in this case is the pharmaceutical industry, has a legal obligation to buy Products Liability insurance for its responsibility, which means up to DM 200m per drug.

Thus in 1975/76 the German insurance industry found itself confronted with the task of having to insure the very strict liability for a particular exposed risk and this, at particularly high sums insured. In addition to this, we were obliged to accept every pharmaceutical entrepreneur, it was not possible to set a yearly aggregate limit and there were no exclusions allowed whatsoever.

What became apparent in a very short time was that, for example, medium-sized pharmaceutical companies (of which there are several hundred) would be the ones who had the most trouble insuring their risk without exclusions, without aggregate limits and other complications at acceptable premiums and placing 100%.

This gave rise to the idea of combining the capacity of the German market and interested foreign insurers to provide a reliable and enduring guarantee that the requirements of the law would be fulfilled for every pharmaceutical entrepreneur, from the smallest to the giants. A pool was to be created in which all insurance companies were to participate and which was meant to give reinsurance protection to the individual member in respect of its German pharma business. At the same time, the pool was to be tied to the international insurance and reinsurance market. Munich Re. had a decisive influence both on the development of this plan and in its successful realization. This is why Munich Re was asked to take over the management of the pool. The Parmapool was officially established in the offices of Munich Re in 1976.

It is an association or company, whatever the correct expression may be, of approximately 120 insurance companies from 11 European countries. The Pool's exclusive business is the reinsurance, I repeat, the reinsurance of Pharma-Products Liability business according to the requirements of the German Pharmaceutical Act.

To state it very clearly:

The Germany Pharmapool does not reinsure policies which have been issued in other countries for foreign producers, but covers only the insurances prescribed by the Pharmaceutical Act for pharmaceutical entrepreneurs operating in or importing to Germany.

Here I have come to the second part of may talk, namely the structure of the Pharmapool and the details of its work.

First of all I must emphasize that the Pharmapool is an autonomous organisation. It exists independently of MR, so to speak, alongside it. Munich Re is just a member like the other 120 member companies, except that it is the managing member company in addition to this. The Pool has its own bank account, its own accounting, its own personnel, etc. Its personnel staff was delegated from Munich Re to the Pharmapool. The Pool has its offices in the buildings of the Munich Re main office.

This makes it possible for us to utilize all facilities of Munich Re from the telephone to the legal department, MR computers, etc. Of course, the Pool has to reimburse the MR for all costs of using these facilities.

The Pool has an Executive Board consisting of five members. Each of these is a member of the Executive Board of a member company, among them one of Munich Re's Executive Board. This Executive Board directs the Pool. A delegated staff member from Munich Re is appointed Executive Manager of the pool. He has to prepare the decisions of the Board, to carry out these decisions, and to direct the administration of the Pool.

Another important point is that the Pharmapool has an advisory council, made up of 10 representatives from all groups of the insureds, ranging from large to medium-sized producers, down to

druggists or chemists. The Council only has an advisory function. I will take this up again in the third part of my talk.

The Pharmapool's statutes say that the Pool gives all members reinsurance amounting to DM 190 m in excess of DM 10 m per drug. Non-members can also be reinsured on a facultative basis. Every member is liable for the share in the Pool it has written for every loss and he receives a proportional share in the premiums and results.

Of significance here is that the members, according to the statutes, are obliged to apply the premiums, rates and conditions set by the Pharmapool for the layer of DM 190 m. Discounts from these rates are not permissible. If an insurer does not use the rates set by the Pool, he loses his reinsurance protection.

Without these strict terms, it would not have been possible to bring and keep the Pharmapool's 120 members together. If these guidelines had not been set, it is certain that premiums would constantly have been underbid and insurance conditions extended which might have led to the cancellation of membership of other companies.

On the other hand policyholders are still being competed for, because primary insurers have a free hand in premiums for the first DM 10 m. The Pharmapool is not involved in this layer, which can be reinsured in the usual way.

There are still a number of other important conditions which are necessary to keep the system functioning. These I would like to outline just briefly: First of all, every member not only has the possibility of reinsuring with the Pool his pharmaceutical business, he is even obliged to do so. The purpose of this requirement is to prevent the Pool from being burdened with only the most hazardous risk, while less hazardous risks like minor producers who process something

along the lines of peppermint tea are not ceded to the Pool. This would create an extremely negative risk selection for the Pool.

Another important condition states that every member must bear its own share in the Pool on a net basis, that means, it is not allowed to take out reinsurance on this shares. At the time the Pool was founded we had to greatly emphasize the importance of this point because the Pool as a body was interested in buying retrocession on the international retrocession market. We were and are interested in protecting the retrocessionaires against the danger of accumulation which might have resulted if a member of the Pool reinsured its own share in the Pool in the international market. This net underwriting principle has proven to be very reliable. It has been a great help to the Pharmapool and has made it possible to almost completely place its retrocession even for 1986, in spite of tremendous difficulties on the international market for pharmaceutical business.

The Parmapool has now been in existence for more than 8 years. Some 8,200 risks are insured; of these approximately 1,000 are industrial producers and approximately 7,200 are minor producers, including druggists or chemists.

If I now broach the claims situation, I would like to express myself cautiously: It is a fact that, to date, not a single claim has been reported to the Pharmapool. On the other hand, every Liability insurer knows that in Products Liability insurance and, specifically, in the pharaceutical business there is an exceedingly high risk of losses which have been incurred but not reported. These could still be in the incubation stage, to use a medical jargon.

So much for describing the structure and functioning of the Pharmapool.

This brings me to the last part of my talk, namely to the question of our experience with the Pharmaceutical Act and the Pharmapool.

First of all there is one point I would like to clearly emphasize and this is of course not a merit of Pharmapool, but rather of the German legislative body, or the authorities and, last but not least, the German pharmaceutical industry:

The level of drug safety, which has always acutally been very high despite the case of Contergan, was once again increased considerably as a result of the introduction of the Pharmaceutical Act. This naturally does not mean that no exposure is left. There are naturally a number of minor loss events which do not however amount to more than a few hundred thousand Deutschmarks per event. But I consider it to be significant that over the past 8 years not one single report for any claim in excess of DM 1 m has been filed with us, even though the entire German pharmaceutical industry and all small pharmaceutical entrepreneurs with no exception whatsoever are insured with us.

A second important part of experience which is directly connected with the Pharmapool deserves mention here: the Pharmapool with its very strict rules in respect of premium rates, policy-wording etc. is the ideal instrument for building up premium reserves over a period of many years for these exceedingly hazardous risks. The Pool is therefore able to provide long-term security without problems like hectic premium fluctuations or periods of tight capacity.

Let me explain this a little further: We all know that upper layers of large policies often go for years without being burdened by one single claim, partly for the fortunate reason that major losses do not occur very often and, partly, they do not come to light until years later. Those (apparently) claims-free periods of such layers are of course exploited by brokers and policyholders to reduce premiums and to extend

conditions. As a consequence, premiums generally slip downwards and there are no adequate premium reserves available for that Day of Judgement when big claims or even catastrophe claims become known.

This problem of a period of years which seem to be free of claims, and dropping rates, is especially threatening in the pharmaceutical business. The keyword "incurred but not reported claims" is familiar to all. But please understand, if I stress this here nevertheless.

In no branch of industry or economy is this problem of IBNR so drastic. The reason for this is that most pharmaceutical bodily injuries are caused by the use of drugs over a long period of time. This especially applies to drugs for rheumatism, for heart and circulatory disorders and to many other powerful drugs. Even if liver or intestinal damage develops after years of continuous use, many patients do not recognise that the drug was the cause of their injury and years pass again before epidemiological studies uncover the relevance and claims are filed.

Another cause of "incurred but not reported losses" lies in the fact that damage to health often does not occur until many years after the drug has been used. A prime example of this is the DES case. In the 1940's expectant mothers took the medication and the female child which was born appeared to be completely healthy. It was not until 14 or 15 years later, namely at puberty, that the child contracted a special form of cancer as a consequence of the mother's having taken the drug DES.

It can indeed be stated that most pharmaceutical losses, maybe even the great majority, are "Spätschäden" as we in Germany call losses which have been incurred but not yet reported and that the business is of extreme long-tail-character.

This leads us to one of the most important underwriting conclusions for the area of pharmaceuticals, which is that we must not bow to the understandable urging of the insured parties and brokers to reduce premiums after a number of claims-free years. Fortunately, the Pharmapool has correctly assessed and dealt with this in the interest of all participants.

There have naturally been attempts which in fact are becoming more persistent from year to year to convince us to reduce the Pool rates, since no losses have apparently been incurred. But in this respect another precautionary measure has had a very positive effect: As early as 1977, the Executive Board of the Pharmapool created the Advisory Council mentioned earlier as a forum of co-operation with the insured parties. This Council is made up of representatives from pharmaceutical industry associations, representatives from large pharmacists. This Council meets retularly with the Executive Board and Mangement of the Pharmapool to discuss the development of risk, the development of legislation and Court decisions, premium questions and other problems. It is true that there were difficulties and certain tensions at the beginning. As years passed however, the co-operative effort which developed was definitely good, even excellent, and made it possible for us to find solutions to all problems and even the difficult premium questions that were more or less satisfactory to all participants. Through this body it was possible to make the insured parties understand this it is in their interest too, to have the Pharmapool accumulate reserves for any potential "incurred but not reported losses" or for catastrophe losses.

How well the Pharmapool functions and how it enjoys the trust for example of the London market is shown by the fact that the Pharmapool was able to almost completely place its retrocession on the London market, without being hindered by the premium increases and capacity problems of the last few months.

Let me point out still another advantage of the Pharmapool:

We as a specialised reinsurer have the opportunity which an insurer rarely has otherwise to deal in detail with both the technical aspects of the risk, meaning with pharmacology, with medical problems, with scientific development, as well as with the underwriting aspects, which includes the development of new clauses, new insurance principles, etc. I am no physician or pharmacologist, but a lawyer and, for this reason, I had no idea at the beginning of how a drug actually functions, how it is tested, etc. But over the years, we have learned more and more about these questions and now have more knowledge about pharmaceuticals than ever before.

In this way I hope that we are in a position to be a relatively competent and understanding partner to an important branch of the industry.

In conclusion let me just state very briefly that the Pharmaceutical Act also prescribes obligatory insurance for the clinical testing of drugs. We have created a special institution for this as well, based on our positive experiences with the Pharmapool. This is known as the "Proband cover", which reinsures policies for human "guinea pigs". I hope I use this expression correctly, but I am told that it is quite common in English. This "Proband cover" deals exclusively with insurances for testing new or modified drugs on humans. Here as well, Munich Reinsurance Company is the Managing Member and the "Proband cover" is administered by the same personnel which handles the Pharmapool. We have already insured more than 300,000 probands and, fortunately, there have been no claims filed to date.

I hope that I have given you an idea of the more important points of the Pharmapool and its experience. Thank you very much for your attention.