

***Case No COMP/M.3751 -
NOVARTIS / HEXAL***

Only the English text is available and authentic.

**REGULATION (EC) No 139/2004
MERGER PROCEDURE**

Article 6(2) NON-OPPOSITION
Date: 27/05/2005

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 27/V/2005

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In the published version of this decision, some information has been omitted pursuant to Article 17(2) of Council Regulation (EEC) No 139/2004 concerning non-disclosure of business secrets and other confidential information. The omissions are shown thus [...]. Where possible the information omitted has been replaced by ranges of figures or a general description.

PUBLIC VERSION

MERGER PROCEDURE
ARTICLES 6(1)(b) & 6(2)
DECISION

To the notifying party

**Subject: Case No COMP/M.3751-Novartis/Hexal
Notification of 04.04.2005 pursuant to Article 4 of Council Regulation
No 139/2004¹**

On 04.04.2005, the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 by which the undertaking Novartis AG (“Novartis”, Switzerland) acquires within the meaning of Article 3(1)(b) of the Council Regulation control of the whole of the undertaking Hexal AG (“Hexal”, Germany) and Eon Labs (USA) by way of purchase of shares.

1. In the course of the proceedings, the notifying party submitted undertakings designed to eliminate competition concerns identified by the Commission, in accordance with Article 6(2) of the Merger Regulation. In the light of these modifications, the Commission has concluded that the notified operation falls within the scope of the Merger Regulation and does not raise serious doubts as to its compatibility with the common market and with the functioning of the EEA Agreement.

I. THE PARTIES

Novartis is the Swiss-based holding of a multinational group of companies engaged in the production and distribution of medical products, including prescription drugs, OTC drugs and animal health products. The Sandoz division of the company is one of the largest generic producers in EEA.

Hexal is a privately owned company active globally in the development, production and marketing of generic medications and innovative pharmaceutical preparations. Hexal

¹ OJ L 24, 29.1.2004 p. 1.

has a sister company named Eon Labs which is a pharmaceutical company engaged in generic medicines exclusively in the US and with no activities in Europe.

II. THE OPERATION

Novartis intends to acquire sole control over Hexal and will acquire 100% of the shares in [...] from the Strüngmann family [...].

Shortly afterwards and conditioned upon the Novartis/Hexal transaction, Novartis will acquire 67.5% of the capital stock of Eon Labs held by Santo Holding AG Switzerland, which is indirectly solely controlled by the Strüngmann family. Furthermore, Novartis will launch a tender offer to acquire the remainder of the Eon Lab's shares. However, by the acquisition of the 67.5% shareholding, Novartis will also acquire sole control over Eon Labs.

III. CONCENTRATION

The transaction relates to the acquisition of sole control of Hexal and Eon Labs by Novartis and constitutes therefore a concentration within the meaning of Article 3 (1)(b) of the Merger Regulation.

The Novartis/Eon labs transaction is considered as being part of the same concentration based on Art 5(2) 2 of the Merger Regulation as both transactions involve the same buyer (Novartis) and the same seller (the Strüngmann family [...]).

IV. COMMUNITY DIMENSION

The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 billion² (Novartis 22,742 million euro, Hexal/Eon labs [...] million euro). Each of Novartis and Hexal have a Community-wide turnover in excess of EUR 250 million (Novartis [...] million euro, Hexal [...] million), but they do not achieve more than two-thirds of their aggregate Community-wide turnover within one and the same Member State. The notified operation therefore has a Community dimension.

V. COMPETITIVE ASSESSMENT

A. Overview

The concentration refers almost exclusively to generics, as Hexal is generally not active in the production and marketing of originator drugs. Novartis (Sandoz) is active in both fields, and intends to participate in the growth of generics in the future. Eon Labs has no activities in Europe and neither manufactures any active ingredients and therefore its activities will not be further analysed.

The transaction will create the largest producer of generics on worldwide and European level. However, a significant number of other generic producers compete with the merged entity. The concentration will lead to a significant number of affected markets, but only in 3 affected markets competition concerns have been identified.

B. Horizontally related markets

² Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Notice on the calculation of turnover (OJ C66, 2.3.1998, p25).

RELEVANT PRODUCT MARKETS

ATC-3 level

2. In previous decisions³, the Commission noted that medicines may be subdivided into therapeutic classes by reference to the “Anatomical Therapeutic Chemical” classification (ATC), devised by European Pharmaceutical Marketing Research Association (EphMRA) and maintained by EphMRA and Intercontinental Medical Statistics (IMS). The ATC is hierarchical and has 16 categories (A, B, C, D, etc.) each with up to four levels. The first level (ATC 1) is the most general and the fourth level (ATC 4) the most detailed. The third ATC level allows medicines to be grouped in terms of their therapeutic indications, i.e. their intended use. This level is generally used as the starting point for defining and enquiring about market definition in competition cases. However, it is appropriate to carry out analyses at other ATC levels, or a mixture thereof, if the circumstances of a case show that sufficiently strong competitive constraints faced by the undertakings involved are situated at another level, and that, therefore, there are indications that the third ATC level does not lead to a correct market definition.

Prescribed/non-prescribed (OTC)

3. The Commission has in the past⁴ defined separate markets for OTC (as opposed to prescription) pharmaceuticals because medical indications (as well as side effects), legal framework, marketing and distributing tend to differ between these categories, even if the active ingredients are identical. OTC products may be advertised to the public at large. Doctors do not need to intervene in the purchase of these products. Consumers make their own choice and bear the costs of their purchase, generally leading to a higher price elasticity of demand. By contrast, prescription pharmaceuticals need to be prescribed by a doctor, whose intervention is thus essential in the choice of the product. Pricing for prescription products is influenced by the public health care system, who pays (part of) the purchase price via reimbursement. Marketing, therefore, is targeted at prescribers, that is, doctors and hospitals. “Semi-ethical” products are OTC drugs for which reimbursement can be obtained if they are purchased on prescription. In the present case, the market investigation has largely confirmed that prescription and OTC products constitute separate product markets.

Originator medicines/generics

In previous decisions, the Commission has never made a distinction between generics and originator drugs. The competitive assessment was generally based on all medicines but when assessing the competitive situation in a given market, the Commission took into account the fact that parties’ originator drugs were exposed to generic competition. Generics are in general less expensive copies of the originator drugs. In regulatory approval procedures, a generic drug manufacturer has to demonstrate that the generic version of the originator drug has identical quality and purity and is biologically equivalent to the originator drug.

³ COMP M.3544 – Bayer Healthcare/Roche, COMP M.3354-Sanofi-Synthelabo/Aventis

⁴ COMP M.3544 – Bayer Healthcare/Roche, COMP/M.3394 – Johnson & Johnson/ Johnson & Johnson MSD Europe

The parties submit that originator drugs and generics for a given indication are part of the same market. They are fully substitutable from the customer's or the prescribing doctor's point of view. Almost all off-patent medicines are available both as originator medicines and as generics. The parties also submit that the originator drug quickly and significantly loses market share once generics are launched in the market, unless its prices are reduced.

The market investigation has confirmed the views of the parties and has indicated that generics can efficiently substitute originator drugs after patent expiry, especially if the regulatory background pushes for switching.

The more specific characteristics of each affected market will be described in the assessment part of this decision.

RELEVANT GEOGRAPHIC MARKETS

4. The Commission has previously defined the geographic markets for pharmaceutical products as being national in scope, despite the trend towards harmonisation at a European level. The parties submit that certain developments in recent years may point to a broader geographic market, but have accepted also the approach of the Commission.
5. The results of the investigation suggest that the Commission should not deviate from its previous practice in assessing pharmaceutical markets at the national level and that the same approach is appropriate for generic products. At this stage, despite the presence of large European wholesalers, the competition still takes place at national level.

B. Vertically related markets

In previous decisions⁵ the Commission concluded that active ingredients form a separate market which is upstream of the market of the finished pharmaceutical products. The market investigation in this case has confirmed this approach.

The Commission has also found that active ingredients markets are, from a geographic scope, larger than markets for finished pharmaceutical products and may be worldwide. The market investigation has confirmed this.

While both parties are active in the production of active ingredients, Hexal uses its entire production internally and does not sell these substances to third parties. Novartis sells active ingredients to third parties. Eon Labs does not produce active ingredients.

Vertically affected upstream markets will only be created with respect to the active ingredients flucloxacillin, oxacillin, penicillin V and tyronine.

C. Assessment

Horizontally affected markets

Based on the ATC 3 categories, the concentration will create 111 horizontally affected markets in the area of medicines. The parties state that the market shares in most cases are either significantly below 35% or the increment in market share is less than 1%. Most affected markets are in Germany. The calculation of the market shares is based on the IMS MIDAS database and the market volumes are extrapolated from market volumes for the first three quarters of 2004, as volumes for the entire year 2004 were not yet available.

In the course of the investigation, the Commission has identified 17 potential Group 1 markets (market share above 35% and increment above 1%) which are discussed in detail below and the market investigation was focused on these markets. With regard to the remaining 94 Group 2 (market share above 35% and increment below 1%) and Group 3 (market share below 35%) markets, third parties did not indicate any competition problems on these markets. In only 3 Group 1 markets the concentration would result in competition problems. However, the parties have submitted remedies in order to remove the overlap in these markets.

OTC A2B (Anti-Ulcerants) in Denmark

Anti-ulcerants encompass a variety of drugs used to treat stomach ulcers considered to be related to acid secretion. Mainly the different mode of action of these products puts into question whether the ATC 3 class should be considered as the relevant product market.

One alternative could be to define the market on ATC 4 level. The OTC products in the A2B category that are available in Denmark are all grouped in the ATC 4 classes A2B1 (H2 antagonists) and A2B9 (all other antiulcerants). H2 antagonists (A2B1) act upon the stomach's acid production process. They exist as prescription bound drugs and in lower doses as OTC. The group A2B9 in Denmark consists of two OTC products based

⁵ COMP M.3394 – Johnson&Johnson/Johnson&Johnson MSD Europe, decision 29.03.2004

on the active ingredient sulcrafat. These drugs stimulate the protection of the gastric mucosa and build a specific kind of protective layer.

In the recent *Bayer Healthcare/Roche (OTC Business)* decision however, the Commission stated that there were strong indications for a relevant OTC product market comprising on the ATC 4 level H2 antagonists (A2B1) and antacids (ATC 4 category A2A1).⁶ Antacids neutralize, in one way or another, excess acids. Although H2 antagonists (A2B1) may be considered as “stronger” drugs, the lower dosages authorized for OTC sale are indicated for similar gravities of diseases.

However, the market definition can be left open for the purpose of this decision since serious competition concerns due to the transaction do not arise whatever market definition is taken.

With respect to all OTC drugs in the ATC 3 class A2B the Parties had a combined share of [60-65]% (Novartis [0-5]%, Hexal [55-60]%). The total volume of OTC drugs in the ATC 3 class A2B amounted to Euro [1.3-1.5] million. The Parties’ products are all generics. They are active mainly with H2 antagonists (A2B1), which are all based on the active ingredients ranitidine and cimetidine. Only Novartis is active with a sucralfate product “Hexagaston”. Other major competitors in this area were GlaxoSmithKline ([10-15]%) with the H2 antagonists Zantac (ranitidine) and Novamed (cimetidine), Paranova ([10-15]%) with the H2 antagonist Zantac (ranitidine) and Orion ([5-10]%) with Antepsin (sucralfate). Several other players are on the market with generic H2 antagonists based on the active ingredients ranitidine and cimetidin.

Although the notified transaction will strengthen the leadership of Novartis/Hexal in Denmark with respect to market share, the limited overlap in terms of market share and value (Euro [...]) does not significantly strengthen the pre-merger position of Hexal. The Parties face strong competition by several originator and generic drugs based on the same active ingredients. Third parties in their replies to the Commission’s questionnaire have not revealed substantial competition concerns in this market and no specific entry barriers were mentioned. Hence, the market investigation has found no indication that competition might be significantly impeded as a result of the notified transaction.

Based on ATC 4 subgroups, the competitive structure and hence the assessment of the market does not differ significantly. Based on ATC 4 A2B1 (H2 antagonists), the combined market share would be [60-65]% (Hexal: [60-65] %; Novartis [0-5]%), the total market volume [1.2-1.4] million Euro. Based on ATC 4 A2A9 there would be no competition concerns as the parties products do not overlap in this category.

Adding up antacids (ATC 4 category A2A1) to the H2 antagonists (A2B1) would reduce the Parties combined market share significantly to [15-20]% (Novartis [0-5]%, Hexal [10-15]%)⁷.

⁶ COMP/M.3544 – *Bayer Healthcare/Roche (OTC Business)*, para. 20.

⁷ The market investigation did not reveal that the A2B9 group should be added to this indication based market definition, where antacids (A2A1) are included. Anyhow the addition would not change the competitive assessment of this composed market. Adding the ATC 4 category A2B9 would result in a combined market share of [15-20]% (Novartis [0-5]%, Hexal [10-15]%,).

OTC D6D (Topical Viral Infection Products) in Denmark

The D6D ATC 3 class includes products for the topical treatment of viral infections. The principal use of these products is in the treatment of herpes labialis (cold sores) and genital herpes. In its previous decision the Commission⁸ identified the ATC-3 as appropriate market definition for the D6D market. The majority of third parties contacted confirmed this approach and neither the parties nor the investigation proposed wider or narrower definitions.

The Parties reported significant market shares only for the OTC market in Denmark. In 2004, the Parties' combined market for ATC 3 class D6D amounted to [50-55]% (Novartis: [35-40]%, Hexal: [10-15]%), however the total market size reached only EUR 0.6 million. The largest competitors were Stada ([30-35]%) and GlaxoSmithKline ([15-20]%).

The investigation confirmed the presence and market position of the competitors. The majority of the third parties stated that the new retail opportunities were opened up in 2001 and increased competition. As a consequence, Hexal's market share dropped significantly decreasing from [35-40]% (2002). Third parties further confirmed that the merger would not lead to anticompetitive effects on this market. In the light of the foregoing, the Commission has concluded that no competition concerns are likely to arise on this market.

Prescription H4A (Calcitonins) in Germany and Poland

The ATC 3 category H4A includes all calcitonin products (i.e., of natural and synthetic origin). Calcitonin is a hormone that occurs naturally in the human body and inhibits bone resorption by acting on specific receptors on osteoclasts. Calcitonins are thus used primarily for the treatment of osteoporosis. Another, much smaller indication area is Paget's disease.

The Parties submitted that the ATC 3 category H4A does not accurately reflect the relevant product market and referred to the one of the previous cases of the Commission. In Ciba-Geigy/Sandoz⁹, the Commission stated that the relevant product market definition should also include the so-called "diphosphonates"¹⁰ falling into the ATC 3 category M5B (bone calcium regulators) for the Swedish and the Dutch markets. Although these products may be substituted with each other, the Commission did not deny the existence of "fluid" boundaries between these products, which are mainly due to "cost considerations, the experience and training of the doctor, differences between national schools and the patient's key symptoms".¹¹

Although the market investigation confirmed that there is a gradual replacing process between the traditional calcitonin therapy and bisphosphonates, the majority of third parties proposed narrow H4A market definition for Poland and Germany. It has been

⁸ Case COMP M.1846 Glaxo Wellcome/SmithKline Beecham, para 31

⁹ Case IV/M.737 Ciba-Geigy/Sandoz, para. 29,32.

¹⁰ The bisphosphonates were called diphosphantes at that time.

¹¹ Case IV/M.737 Ciba-Geigy/Sandoz, para. 31.

argued that the boundaries of the indication-based product market definition and the extent of the substitutability¹² of these products were not clear, and possibly not all M5B products could be included.

The parties indicated that 55-60% of sales of M5B should be attached to H4A ATC-3 class, arguing that most probably this is the right amount of drugs, which are possibly substitutable with H4A for the treatment of osteoporosis. The parties also submitted that the rest of the M5B class was mainly used for the treatment of bone cancer.

The investigation did not confirm the parties' proposition for splitting up the M5B class to cancer treatment drugs (up to 40% of M5B sales) and to osteoporosis drugs (up to 60%). Most third parties argued that calcitonins were hormones and medicaments with stronger side effects than bisphosphonates. It was also argued that one patient using M5B medicines for cancer treatment used almost the same amount of medicine than 10 patients cured with osteoporosis. Therefore, third parties argued that the boundaries between the H4A and M5B class medicines cannot be defined and the boundary would be very fluid. A market definition based on an ATC-4 class would not be adequate either, since the drugs grouped in M5B class should be assessed one by one based on their indication and real use (osteoporosis versus cancer).

In order to support their initial approach of market definition, the parties gave additional information to the Commission. They argued that during the past five years the size of the H4A market strongly declined in favour of bisphosphonates drugs and in addition the medicines available in the M5B group were proved to be more modern and preferred by the doctors in the treatment of the osteoporosis (than those grouped in the H4A class).

The IMS statistics submitted by the parties and the additional investigation of the Commission supported the decline of the H4A market. Clearly, the H4A market was declining in the past years and is still under a consolidation process; however it remained unclear whether the H4A market may disappear completely or will become a mini market with a limited number of drugs whose substitution with M5B osteoporosis products is questionable. It was however confirmed by the investigation that at this stage of the consolidation the weak brands left the H4A market, whereas the strongest brands remained and kept or even raised their market shares to the detriment of the weaker brands present in this class. It can also be argued that the calcitonin products remaining on the market were already showing a limited substitution vis-à-vis to M5B drugs.

Since there were strong indications for a narrower product market definition for the treatment of osteoporosis in Poland and Germany, the Commission based its assessment on the H4A market.

Based on H4A market definition the concentration would result in high market shares in Germany. The parties had a combined market share of [70-75]% (Novartis [70-75]%, Hexal [0-5]%) in 2004. The main competitor was Merckle with Calcitonin ([20-25]%). The market volume amounted to Euro [5-6] million. During its investigation the Commission considered that the small increment of Hexal would not materially influence the strategy of the merged entity, especially in the light that Hexal lost

¹² In Northern European countries bisphosphonates substituted far more the calcitonins than in Southern Europe.

important market shares in the past years declining from [5-10]% (2000) to [0-5]% (2004). In the light of the foregoing, the concentration will change neither the market structure nor the behaviour of the market leader materially, and therefore no competition concerns can be addressed as the outcome of the concentration in Germany. Under the alternative market definition proposed by the parties the concentration would not give rise at all to competition concerns (Combined market share: [30-35]%/ Novartis: [30-35]%/ Hexal: [0-5]%).

In Poland, on the basis of an H4A market alone, the combined market share of the parties amounted to [80-85]% (Novartis: [40-45]%, Hexal: [40-45]%) in 2004. The Parties' main competitor in this segment was Jelfa ([15-20]%) and to a limited extent Alfa Wasserman (below 2%). The market volume amounted to almost Euro [1.8-2.2] million in 2004.

On this market, Hexal is considered as a strong generic brand opposed to its position in Germany and with equal shares to the holder of the originator brand. The decreasing size of the market itself cannot remedy the high market share of the parties, which may be even more accentuated after the consolidation of these markets. In shrinking markets it is still possible for a dominant firm to exploit its market power. This aspect has been underlined by third parties. It was explained that after the withdrawal of the weak generics the remaining brands could gain returns on the declining market.

Under these circumstances the merger would create a market leader long ahead its competitors and marketing the strongest brands, which would result in serious doubts regarding the creation of single dominance of the parties in this market. Therefore, the merged entity could definitely benefit from the declining output conditions of the Polish H4A market by raising prices.

Based on the above, the operation raises serious doubts with regard to the Polish prescription H4A market as to its compatibility with the Common market

Prescription L4A (Immunosuppressive Agents) in Latvia / Lithuania

Immunosuppressives are substances used to prevent the production of antibodies. The market may be subdivided into so-called primary immunosuppressants, accompanying or adjunctive immunosuppressants, and induction immunosuppressants, mainly due to their application at the different stages of the therapy against transplant rejection. Immunosuppressants can be used also for other indications like, treatment of severe eczema or other autoimmune diseases (e.g. rheumatoid arthritis). The investigation confirmed that the product market is not wider than L4A. A number of third parties did not oppose a possible subdivision of the market into primary, accompanying and induction L4A products. Since the concentration does not give rise to serious concerns these market definitions will be left open for the purposes of this case.

Based on L4A category, the parties' combined shares amounted to [55-60]% (Novartis: [55-60]% and Hexal: [0-5]%) in 2004 in Latvia. The main competitors were GlaxoSmithKline ([25-30]%) and Roche ([10-15]%), while the total volume of the L4A market remained very small, up to EUR [70,000-80,000]. Subdividing the L4A group, parties' activities would overlap only in the area of adjunctive immunosuppression. On this sub-market, the combined share of the parties was about [45-50]% (Novartis: [45-50]% and Hexal: [0-5]%) in 2004. The largest competitors

were GlaxoSmithKline ([30-35]%) and Roche ([15-20]%) on a market with a volume of Euro [50,000-60,000].

The market investigation has confirmed the presence of these competitors and of new drugs entering or on their way to entering this market. Third parties did not identify competition concerns on this market; and there is still a lot of room for changes in the L4A segment, considering that in 2002 one company almost dominated the whole market. Therefore, the Commission has concluded that no competition concerns are likely to arise on the Latvian market.

In Lithuania the parties' combined market share on the entire L4A market amounted to [35-40]% (Novartis: [25-30]% and Hexal: [5-10]%). Parties' competitors achieved important market shares, like Roche ([40-45]%) and Schering Plough ([15-20]%). The size of the market was almost Euro [1.8-2.2] million in 2004. According to the narrower market definition, the parties combined share was [55-60]% in 2004 (Novartis: [40-45]%. and Hexal: [15-20]%) for L4A primary immunosuppression, which is the only segment where parties overlap. The competitors remained the same with slightly lower shares, for example Schering Plough ([30-35]%) and Roche ([5-10]%). The size of the market amounted to EUR [1.1-1.3] million.

The market investigation confirmed that the parties' combined market share increased over [50-55]% when a narrow market definition has been adopted. Even under that circumstance the competitors remained with important market shares and stable positions. Third parties did not identify any barriers to entry or any competition concern for any of the L4A segments in Lithuania. Therefore, the Commission has concluded that no competition concerns are likely to arise on the Lithuanian market.

OTC M2A (Topical Anti-Rheumatics) in Germany and Lithuania

This category includes ointments, creams and sprays for the treatment of injuries, sprains, muscular tension etc. The Parties submitted that the ATC 3 level is appropriate to define the relevant market¹³. M2A contains both prescription-bound drugs and OTC drugs. The present case leads to overlaps in the OTC segment in Germany and the prescription bound segment in Lithuania. The market investigation has confirmed that the ATC 3 class M2A is in both areas the adequate market definition. It revealed no indication that any subdivision of the ATC 3 class or a broader approach would be more appropriate to define the relevant product market.

In Germany, this OTC market with a total volume of € [95-115] million, the parties' combined market share amounted to [35-40]% in 2004 (Novartis [35-40]%, Hexal [0-5]%). The largest competitors were Beiersdorf ([5-10]%) and Merckle ([5-10]%), both with a variety of products¹⁴. The parties' market shares have considerably increased from 2002 (Novartis: [20-25]%, Hexal: [0-5]%).

Despite the relatively limited combined market share the market investigation has revealed serious concerns in this market related to possible unilateral effects created by the merger.

¹³ The ATC classification devised by EphMRA does not further subdivide the ATC 3 class M2A on an ATC 4 level.

¹⁴ Beiersdorf mainly with "Hansaplast" products ([5-10]%); Merckle mainly with the originator brand Dolobene ([0-5]%).

Novartis is the undisputed market leader with its brand “Voltaren” (market share 2004 [30-35]%)¹⁵. Hexal’s generic version “Diclac” is generally considered as a strong generic brand, which has grown its market share based on substantial investments in TV advertisements and is still growing. Third parties have argued that “Diclac” is the closest substitute to “Voltaren”. Certain other existing products on the market, in particular Beiersdorf’s “Hansaplast” and Merckle’s “Dolobene” also appear to be strong brands. However, they are not close substitutes to “Voltaren” as they are not based on the same active ingredient as “Diclac” and “Voltaren”.

The concentration would therefore combine two products which a substantial number of consumers would regard as their first and second choice. In such a situation, the parties have an incentive to increase prices post-merger. New entrants on the market were considered as not very likely due to the high level of advertising costs to promote a new brand.

In addition, the combination of the leading originator brand with the leading generic would give the parties the opportunity to offer package deals to pharmacies and to block shelf space. The parties have argued that they could not offer special incentives to pharmacists, as they would keep separate sales forces in order to avoid that the generic product cannibalizes the originator and vice versa. The market investigation however revealed it as likely that the merging parties would try to use their commercial conditions vis-à-vis pharmacies in order to ensure that any substitution away from the originator product “Voltaren” would be in favour of their own generic product. The importance of shelf space was also underlined. Package deals were considered as likely, which would put other brands under promotional pressure and decrease their shelf space.

Based on the above, it can be concluded that the proposed concentration raises serious doubts with regard to the German OTC M2A market as to its compatibility with the common market.

The prescription bound M2A market in Lituania is a rather small market with a total volume of Euro [0.4-0.6] million. The Parties’ combined market share amounts to [60-65]% in 2004 (Novartis [0-5] %, Hexal [55-60] %). The parties would face competition by Actavis ([35-40]%), Gedeon Richter ([0-5]%) and Baktaris ([0-5]%). The market investigation revealed no specific entry barriers. All drugs in this category are generics. Baktaris is a new entrant that gained its market share within one year. According to the market investigation at least one other competitor intends to introduce new generic products on the market. During the market investigation third parties have expressed no negative comments regarding the transaction. Therefore, no serious doubts with regard to the operation’s compatibility with the Common Market arise in this market.

Prescription M3B (Muscle Relaxants, Centrally Acting) in the Netherlands

The ATC 3 class M3B encompasses centrally acting muscle relaxants. These are drugs that relax striated muscles (those that control the skeleton). Skeletal muscle relaxants may be used for relief of spasticity in neuromuscular diseases as multiple sclerosis, as well as for spinal cord injury and stroke. They may also be used for pain relief in minor strain injuries. In previous decisions the Commission has discussed the subdivision of this ATC 3 class, but has left the market definition open. In Ciba-Geigy/Sandoz it was

¹⁵ Novartis is active with a variety of other drugs on the market, each with less than [0-5]% market share.

considered to distinguish in two separate markets for a) products for the treatment of spasticity in CNS diseases and b) products for the treatment of simple muscle spasms¹⁶. In Sanofi-Synthelabo/Aventis it was considered to define a different market for products based on the active ingredient baclofen¹⁷.

The parties considered it appropriate to define a separate product market for baclofen products. They argued that it is not possible to break down the market into products for the treatment of spasticity in CNS diseases on the one hand and products for the treatment of simple muscle spasms on the other hand, as most products in the relevant category are indicated for both indications. This factual argument was confirmed by the market investigation.

The market investigation also revealed that the therapeutic indication of baclofen products is specifically limited to spasticity of cerebral origin whereas other products in the ATC 3 class M3B are indicated for treatments of additional diseases. It can however be left open for the purpose of this case, whether the ATC 3 class should be accordingly subdivided and a different market for baclofen products be defined, since the competitive analysis would not change significantly.

On the overall prescription M3B market with a volume of Euro [1.5-1.7] million the parties had a combined share of [45-50]% (Novartis [45-50]%, Hexal [0-5]%). Novartis is on the market with two originator drugs Lioresal (baclofen) and Sirdalud (tizanidine) and a generic drug (baclofen), Hexal with the generic drug Baclofen – Hexal. The Parties' main competitors were Teva ([15-20]%) and Merckle ([10-15]%) with their generic drugs (baclofen).

Should baclofen form a separate market within M3B, the market volume would be reduced to Euro [1.1-1.3] million. The Parties combined share would amount to only [35-40]% (Novartis [30-35] %, Hexal [0-5]%). Their largest competitors were still Teva ([20-25]%) and Merckle ([15-20] %). In a market excluding baclofen the Parties' products would not overlap. Only Novartis would be active with its drug Sirdalud.

The market investigation has not revealed substantive competition concerns whatever market definition is taken. The limited overlap in terms of market share and value ([...] Euro) will not significantly strengthen the pre-merger position of Novartis. The market investigation revealed that all brands and molecules marketed in this area are out of patent protection. R&D and promotional expenses were considered as low in this area and no specific barriers to entry were mentioned. The parties face strong competition by Teva and Merckle. In addition the market shares of Novartis were decreasing during the last years (2002 *ATC 3 level*: Novartis [55-60] %) due to generic competition. Hexal, who entered the market only 2003, has taken over only small shares of Novartis. Hence, the market investigation has found no indication that competition might be significantly impeded as a result of the notified transaction. It can thus be concluded that no serious doubts as to the compatibility of the operation with the Common market arise.

¹⁶ COMP/M.737 Ciba-Geigy/Sandoz, para 40

¹⁷ COMP/M.3354 Sanofi-Synthelabo/Aventis para 97

Prescription M4A (Anti-Gout Preparations) in Denmark

This ATC 3 class includes drugs against gout. Gout is a systematic disease caused by the deposition of uric acid in the joints. According to the Parties there are various types of drugs used in treating gout which are, however, fully interchangeable and therefore belong to the same product market. On the Danish market only two different product types (products based on the active ingredient “allopurinol” and “rasburicase”) are available.

According to the market investigation there is however a very strong indication that the ATC 3 class should be further subdivided and the market defined as a pure allopurinol market, excluding products based on the active ingredient “rasburicase”, namely the product “Fasturtec”. “Fasturtec” is a product of Sanofi Aventis and the only one based on the active ingredient rasburicase which entered the Danish market in 2000. Both products’ mode of action is to reduce the elevated blood level of uric acid (called hyperuricemia), but they do have different indications. Whereas allopurinol products can be used against chronic hyperuricemia of different geneses, Fasturtec is indicated for the treatment of acute hyperuricemia which is caused as a side effect of chemotherapeutical treatments of hematological cancers. The application of Fasturtec is therefore generally limited to hospitals. The product is applied as infusion once a day over a period of 5-7 days. The price difference to allopurinol products (available as tablets) is huge¹⁸. However, the exact market definition can be left open, since the competitive assessment will not be different whatever market definition.

Already under the broader market definition (ATC 3, market volume €[0.3-0.5] million) the Parties’ combined market share amounted to [65-70]% (Novartis [10-15]%, Hexal [50-55]%). The Parties’ main competitors were Nycomed Pharma ([15-20]%) and Sanofi-Aventis ([10-15]%). Defining the market as a pure allopurinol market would lower the total market volume to Euro [...] million but increase combined market shares to [75-80]% (Novartis [15-20]%, Hexal [60-65]%) with Nycomed Pharma ([20-25]%) remaining the main competitor. Market shares and overlap are thus substantially high under both market definitions.

The parties argued that the prices of the allopurinol products in Denmark are declining heavily due to price erosion which is caused by national reimbursement rules. Up to March 31, 2005, doctors were generally obliged to prescribe only the cheapest drug and pharmacies had the obligation to offer a substitute if the prescription was issued for a more expensive drug. Substitution could be prevented by an explicit remark on the prescription. However, the drug’s full price was borne by the social security system, regardless whether or not it was the cheapest product in the market. Under the new system that came into force on April 1, 2005 the reimbursement is calculated on the basis of the cheapest product in the market. The surplus has to be paid by the patient.

The parties’ arguments were only partly supported by the Commission’s investigation. The Danish system can create the effect of a de facto obstacle to price increases on the market. But the price pressure under this system works only in combination with a sufficient number of players fighting for market shares. Prices of allopurinol products were heavily decreasing during the last years. After the merger, only Nycomed and the parties would be left as substantial players with allopurinol products on the market. A

¹⁸ According to IMS data submitted by the parties, the average price [...] for the allopurinol products and [...] for Fasturtec.

third player, Ivax, can not be considered as a potentially strong competitor. It has only a market share of [0-5]% and does not distribute itself the product on the market. With only two active players left after the transaction, prices could be expected to rise again. Due to the high combined market share of the parties and the diminished competition between the two remaining players on this market, the concentration would threaten to create a position of single dominance of the parties in this market.

Based on the above, it can be concluded that the proposed concentration raises serious doubts with regard to the prescription M4A market in Denmark as to its compatibility with the common market.

Prescription N5B (hypnotics/sedatives) in Denmark

The class N5B contains hypnotics/sedatives, which are drugs against insomnia. In previous decisions¹⁹, the Commission left the question open whether this class should be further subdivided into comparatively expensive modern hypnotics that have light addictive effect and no residue in the morning (non-benzodiazepines), and older hypnotics which are offered at a more moderate price, but have strong potential for causing addiction and have prolonged effects. The parties argue that the products in the two categories are substitutable and the market investigation has given indications that this view can be supported. However, the exact definition of the relevant product market can be left open, since the competitive analysis would not change significantly whatever market definition.

In 2004, the parties combined market share amounted to [45-50]% (Novartis [40-45]%, Hexal [5-10]%). However, a large number of other competitors such as Sanofi-Aventis ([20-25]%), Alpharma ([6-10]%), Nycomed pharma ([0-5]%), Orion ([0-5]%), Roche ([0-5]%), Syntetic ([0-5]%), Stada, Merck, Pfizer, Schering, Paranova and others are active on the market. If one assumed different markets for non-benzodiazepines and benzodiazepines, the competitive situation would not change significantly. In the area of benzodiazepines the combined share (2004) of the parties amounted to [45-50]% (Novartis [35-40]%, Hexal [5-10]%). In the area of non-benzodiazepines, the parties's combined market share amounted to [45-50] % (Novartis [40-45]%, Hexal [5-10]%). The market investigation has confirmed that many other competitors are active in this market, some of them even with pipeline products. Third parties agree with the parties that there are no specific barriers to enter this market in Denmark as all drugs are now out of patent protection and have expressed no negative comments regarding the transaction. Therefore, no serious doubts with regard to the operation's compatibility with the Common Market arise in this market.

OTC N6A (anti-depressants and mood stabilisers) in the Slovak Republic

This class contains anti-depressants and mood stabilisers used to treat mild conditions of depression, low-spiritedness and apathy. In previous decisions²⁰, the Commission conducted its competitive assessment in this area by reference to the (prescription) ATC 3 class N6A. The present case leads to overlaps in the OTC segment, which contains exclusively St.John's Worth extract (hypericum).

¹⁹ COMP M.1397 - Sanofi/Synthelabo, decision 17.05.1999

²⁰ COMP M.1878 – Pfizer/Warner-Lambert, 22.05.2000

In 2004, the parties' combined market share amounted to [70-75]% (Novartis [50-55]%, Hexal [15-20]%). However, the total market volume was marginal in 2004 ([30,000-40,000] euro) and the increment in market share by Hexal was only [...] euro. It has to be noted that in 2002 and 2003, the parties had still a combined market share of 100%, but since then it declined as other competitors gained market share. The major competitor is Lichtwer ([25-30]%) which has entered the market only in 2004 and was already able to achieve a significant market share.

Another product, which is not included in the N6A category but is also an anti-depressant containing hypericum, is Leros's Fytokliman Planta, which in IMS has been attributed to the class V3A. If one includes its sales in the market definition, the parties' combined market share would amount to [60-65]% (Novartis [45-50]%, Hexal [15-20]%). Leros had a market share of [5-10]% and Lichtwer of [20-25]%. The market volume was marginal ([35,000-40,000] euro). Parties also argue that hypericum, in the herbal form, is also sold over other sales channels such as drugstores.

The market investigation has indicated that there are no specific barriers to enter this market in the Slovak Republic and new entrants could gain rapidly a substantial market share. Third parties have expressed no negative comments regarding the transaction and do not expect any impact on prices. Therefore, no serious doubts with regard to the operation's compatibility with the Common Market arise in this market.

Prescription N6B (psychostimulants) in the Netherlands

This class includes psychostimulants which increase the psychic and physical performance and have a fatigue suppressing, stimulating effect and are amphetamine-derivatives. The class N6B in the Netherlands includes only products with the active ingredient methylphenidate, which is used to treat attention deficit hyperactivity disorder (ADHD) in children. While stimulants normally make people more active, stimulants at the doses used for ADHD have the opposite effect. The Commission will assess the effects of this concentration on the prescription N6B market in the Netherlands.

In 2004, the parties' combined market share amounted to [40-45]% (Novartis [25-30]%, Hexal [10-15] %). The leading competitor is J&J ([50-55]%) which has entered the market only in 2003 and has immediately gained a considerable market share at the cost of Novartis. Another competitor is Phoenix Pharmahandel (Merckle) ([0-5]%). It has to be noted that in 2002, Novartis had still a market share of 100% and since then its market share is declining, while the market share of the competitors is rising.

The market investigation has also indicated that there are no specific barriers to enter this market in the Netherlands as all drugs are out of patent protection. In general, no negative comments from third parties regarding the effect of this transaction on this market were received. Therefore, no serious doubts with regard to the operation's compatibility with the Common Market arise in this market.

OTC R6A (Systemic Antihistamines) in Germany and Lithuania

The ATC 3 class R6A contains systemic anti-histamines. These are products used for the treatment of allergic reactions. Anti-histamines act in order to prevent or relieve the typical symptoms of an allergic reaction of the body. The largest part of the ATC 3 class R6A contains lighter anti-histamine products with light sedative effects. In the Parties' view, the relevant market should not include all drugs in this category, but

should be further broken down into sedative and non-sedative anti-histamines taking in consideration that most of the stronger allergy drugs have side effects.

The market investigation did not confirm the proposal of the parties, since most of the third parties argued that the sedative and non-sedative antihistamines could be substituted with each other. Furthermore, it was submitted that even the same patient can take sedative and non-sedative antihistamines simply substituting the products with no particular reason. However it has been admitted that the non-sedative formulas were the most modern, the so-called “second generation” products, and it was also underlined that strong competition has taken place in the sales and marketing but also in the research of these non-sedative preparations. However, the exact market definition can be left open, since the competitive assessment will not be different whatever market definition.

Considering the entire R6A ATC 3 class as the relevant product market, the parties’ combined share would amount to [40-45]% (Novartis: [20-25]% and Hexal: [25-30]%) in Germany. The parties’ largest competitors in this market were Merckle ([15-20]%), UCB ([5-10]%) and Stada ([5-10]%) in Germany in 2004. The market volume was about Euro [50-60] million.

The parties’ combined share for the non-sedating anti-histamines was about [35-40]% (Novartis: [0-5]% and Hexal: [30-35]%) in Germany. The Parties’ largest competitors were Merckle ([20-25]%), UCB ([10-15]%) and Stada ([10-15]%) and the volume of the German market reached Euro [35-50] million in 2004. The parties submitted that no overlap would be generated in the area of sedating histamines, where only Novartis was active.

The market investigation did not indicate competition concerns in Germany. Third parties mentioned that this market was very competitive with more than 30 competitors, and with lots prospects for new products. As a consequence market shares on this market may change rapidly under the pressure and entry of new inventions. In the light of the foregoing, competition concerns are not likely to occur on the German market.

Based on a distinct product market definition for sedating and non-sedating anti-histamines, the parties’ activities would not overlap in Lithuania. Considering the overall R6A ATC 3 class as one market, the parties combined share was of [55-60]% (Novartis: [0-5]% and Hexal: [55-60]%). The largest competitor was KRKA ([40-45]%) with a market size of only Euro [...].

The investigation on the Lithuanian R6A market has demonstrated that no competition concerns were likely to occur on this market either. The investigation confirmed that entry of new drugs is very likely. During the past years the structure of the market has changed and gave room for more players in this segment. In the light of this evidence, the Commission has concluded that no competition concerns are likely to arise on the Lithuanian market.

Prescription S1G (Ocular Anti-Allergics, Decongestants, Antiseptics) in the Czech Republic and OTC S1G in Luxemburg

The ATC 3 class S1G contains ocular anti-allergics, ocular decongestants and ocular antiseptics (eye drops). The Parties submit that the relevant market includes ocular anti-allergics, which would encompass the anti-allergy products in the ATC 3 category S1G (ATC 4 classes S1G1 to S1G3), and the products of the ATC 3 class

S1B (ocular corticoids). The parties further argued that with respect to anti-asthmatics a market definition based on a similar reasoning has not been rejected by the Commission in Case Comp M.1403 Astra/Zeneca.

The market investigation did not confirm this approach. Third parties did not accept any of the market definitions proposed by the parties and found the options either too broad or too narrow. However, the exact market definition can be left open, since the competitive assessment will not be different whatever market definition.

Based on the S1G ATC-3 class product market definition, the parties had a combined share of [70-75]% (Novartis: [60-65]% and Hexal: [10-15]%) on the prescription bound market in the Czech Republic in 2004. The Parties main competitors were Ursapharma ([5-10]%), Nestlé-Alcan ([5-10]%) and Unimed ([5-10]%). The market volume reached Euro [0.7-0.9] million. Under the narrowest market definition, the parties' combined share would not change substantially [75-80]% (Novartis: [65-70]% and Hexal: [10-15]%). The main competitor remaining Ursapharma ([10-15]%) and Nestlé ([5-10]%) and the size of the market would amount up to Euro [600,000-800,000].

The market investigation confirmed parties' high market shares. However, it also confirmed that relatively soon multiple entries are likely to occur on this market. The new products will be mainly new generation drugs, clearly offering better efficacy and better patient outcomes. Most of them have already been introduced in other European countries. It is expected that these products will substantially reduce the parties' market share. The replies also confirmed that most of the parties' drug formulations present on this market are relatively old molecules and would not have a major impact on the future developments on this market. Therefore, the Commission has concluded that no competition concerns are likely to arise on the Czech prescription-bound S1G market.

In Luxemburg parties overlap was limited to the sub-segment of S1G1-S1G3 market. The combined share was of [45-50]% (Novartis: [40-45]% and Hexal: [0-5]%) on the S1G market. On the narrowest possible market (S1G1-S1G3), the parties' combined market share ([45-50]%) would not have changed substantially. For both definitions, the main competitor was Johnson&Johnson ([30-35]%) and Viatrix ([5-10]%) on a market amounting to Euro [300,000-400,000] in 2004.

The market investigation confirmed the presence of these competitors. Third parties did not identify competition concerns on these markets and considered that the structure of the market would not change considerably as the outcome of the transaction. In addition, it has been mentioned that Luxemburg follows not only the European regulations, but also has a legal regime similar to that of the neighbouring countries, which may facilitate the entry of foreign companies. In the light of the foregoing and the small increment of Hexal, the Commission has concluded that no competition concerns are likely to occur on the OTC S1G market in Luxemburg.

Vertically affected markets

Vertically affected upstream markets will only be created with respect to the active ingredients flucloxacillin, oxacillin, penicillin V and tyronine.

Flucloxacillin

Novartis has a worldwide market share (2004) in flucloxacillin of [25-30]%. The parties have indicated that approximately ten other competitors, including Ribbon and Oman, are active on the market. On the relevant downstream ATC-3 market where Hexal is active (prescribed J1H in the Netherlands), the parties' combined market shares (2004) amount to only [0-5]%.

Oxacillin

Novartis has a market share (2004) of [25-30]% in oxacillin. The parties have indicated that approximately ten other competitors, including Bristol-Meyers Squibb, are active on the market. On the relevant downstream ATC-3 market where Hexal is active (prescribed J1H in the Netherlands), the parties' combined market shares (2004) amount to only [0-5]%.

Penicillin V

Novartis has a market share (2004) of [25-30]% in penicillin V. The parties have indicated that approximately five other competitors, including Biotica, NCPC and Kurgan, are active on the market. On the relevant downstream ATC-3 markets where Hexal is active (prescribed J1H in the Netherlands), the parties' combined market shares (2004) amount to only [0-5]%.

Thyronine

Novartis has a market share (2004) of [40-45]% in thyronine. The parties have indicated that approximately three other competitors, including Rhodia and Peptido, are active on the market. On the relevant downstream ATC 3 markets where Hexal is active (prescribed H3A in Germany), the market share (2004) of Hexal is very low (below 5%). Novartis is not active in this segment.

The parties submit that the vertical relationship between Novartis and Hexal does not give rise to competitive concerns in any vertically affected upstream market as the active ingredients mentioned above are freely available from third party sources. Parties' view is that most generic producers, such as Hexal, procure their active ingredients from Eastern Europe, India and China in order to cut their costs. In addition, the parties submit that most of the pharmaceutical companies use dual sourcing for the active ingredients. In addition other suppliers of the above mentioned active ingredients are active on the market.

There are 11 vertically affected downstream markets (A2B, C4A, C7A, C7B, C9A, C10A, J1C, J2A, L2B, M1A, M3B)(all prescribed), including only 1 group I market (prescribed M3B in the Netherlands) where the combined market share of the parties amounts to [45-50]% (Novartis [45-50]%, Hexal [0-5]%). However, on the relevant upstream active ingredient market (baclofen), Novartis' market share is below 25%. The parties argue that the transaction does not raise concerns with respect to the vertically affected downstream markets. The only active ingredients Hexal currently sources from Novartis are certain antibiotics, cimetidine and tyronine. Novartis's worldwide market shares for these active ingredients are low or moderate and other competitors are active on this market.

With regard to vertical relations between active ingredients produced by Novartis and the pharmaceutical products of Hexal, no competition concerns arise from the transaction,

as there are limited market shares downstream or alternative suppliers upstream. The market investigation has not revealed any vertically related competition problems.

Pipeline products (future markets)

Pipeline products are not yet on the market, but are in an advanced stage of development, normally in Phase III clinical trials. Generic companies typically do not conduct R&D as it is understood in the pharmaceutical industry. All of Hexal's pipeline products are generic versions of originator drugs that lose patent protection in the coming years. Competition by other generic companies at that point is foreseeable. Any competitive advantage due to the fact that Novartis could produce its own generic versions of their originators are marginal: While both Sandoz and Hexal plan to launch generic versions of Novartis originator drugs that will go off-patent in the forthcoming years, such products account for a moderate percentage of Sandoz' and Hexal's pipeline products. The remainder of each pipeline consists of generic versions of other manufacturers' originators. For example, only [...] out of [...] new generics Hexal plans to launch in 2005-2009 are generic versions of Novartis originator drugs.

VI. MODIFICATION TO THE PROPOSED OPERATION

6. In order to remove the serious doubts resulting from the proposed transaction, the parties formally submitted commitments to the Commission on 02.05.2005, which were subsequently refined on 25 May 2005. The detailed text of these commitments is annexed to this decision. The full text of the annexed commitments forms an integral part of this decision.

Novartis therefore proposed to divest the following set of assets:

- (i) Hexal's rights to the sale and marketing of Calcihexal (H4A) in Poland (see Schedule I to the annexed commitments);
- (ii) Hexal's rights in the sale and marketing of Diclac (M2A) in Germany (see Schedule II to the annexed commitments); and
- (iii) Hexal's rights in the sale and marketing of Apurin and if requested by the Purchaser Allopurinol (M4A) in Denmark (see Schedule III to the annexed commitments).

These divestitures are accepted on the basis they will transfer a viable going concern to the Purchaser and will thereby remove the entire overlap and transfer Hexal's full market position in the markets of H4A in Poland, of M2A (OTC) in Germany, and significantly decrease or remove the overlap in the market of M4A in Denmark.

7. The Commission considers that the commitments are sufficient to eliminate all serious doubts as to the compatibility of the transaction with the common market. The commitments were supported by third parties in their replies to the Commission's market test.
8. In order to ensure that Novartis complies with these commitments, the Commission attaches conditions and obligations to this decision. The commitments set out in Section B and Schedules I, II and III of the commitments annexed to the present decision constitute conditions, since only by fulfilling them may the structural change on the relevant markets be achieved so as to eliminate the serious doubts identified by the Commission. The other commitments constitute obligations, since they concern the

implementing steps necessary to achieve the structural change intended to eliminate the serious doubts identified by the Commission.

VII. CONCLUSION

9. For the above reasons, the Commission has decided not to oppose the notified operation and to declare it compatible with the common market and with the EEA Agreement, subject to full compliance with: (i) the conditions in Section B and Schedules I to III of the commitments annexed to the present decision; and (ii) the obligations in the other Sections of the said commitments. This decision is adopted in application of Articles 6(1)(b) and 6(2) of Council Regulation (EC) No 139/2004.

(Signed)
Margot WALLSTRÖM
Member of the Commission

Mai 25, 2005

By hand and e-mail:

European Commission
Directorate-General for Competition
Attn. Dr. Joachim Lücking
Rue Joseph II 70

B-1000 Brussels

[...]

COMP/M.3751 - NOVARTIS/HEXAL

COMMITMENTS TO THE EUROPEAN COMMISSION

Pursuant to Articles 6(1)b, 6(2) and 10(2) of Regulation 139/04 (the “*Merger Regulation*”), Novartis AG (“*Novartis*”) and Hexal AG (“*Hexal*”) hereby submit the following commitments (the “*Commitments*”) in order to enable the European Commission to issue its decision (the “*Decision*”) declaring the acquisition of sole control over Hexal by Novartis compatible with the common market and the functioning of the EEA Agreement. The Commitments shall take effect upon the date of adoption of the Decision (the “*Effective Date*”).

SECTION A: DEFINITIONS

For the purpose of the Commitments, the following terms shall be defined as follows:

Affiliated Undertakings: undertakings controlled by the Parties and/or by the ultimate parents of the Parties whereby the notion of control shall be interpreted pursuant to Article 3

of the Merger Regulation and in the light of the Commission's Notice on the concept of concentration under Council Regulation (EEC) No 4064/89.

Assets: all assets referred to under **Section B paragraph 4 (a) to (e)** relating to the Divestment Businesses described in **Schedules I to III**.

Closing: the transfer of the legal title of the Divestment Business to the Purchaser.

Divestment Agreement: the final binding sale and purchase agreement, including any ancillary agreements or licenses, entered into between the Parties and the Purchaser for the transfer of the Divestment Business.

Divestment Business: the one or more businesses defined in **Section B** and **Schedules I to III** hereto that the Parties commit to divest.

Divestiture Trustee: one or more natural or legal person(s), independent from the Parties, approved by the Commission and appointed by Novartis, and who has received from Novartis the exclusive and irrevocable Trustee Mandate to sell the Divestment Business to a Purchaser [...].

First Divestiture Period: a period of [...] months from the Effective Date, which shall be extended automatically for as long as the Commission has not decided on the proposed purchaser(s) submitted by the Parties within [...] months from the Effective Date.

Intellectual Property Rights: subject to **Section B paragraph 6**, all intellectual property rights forming part of a Divestment Business and relating to the research, development, manufacture, sale or use of a Divestment Business product and where relevant its active substances, existing and new formulations and combinations with other active substances, including, but not limited to, existing and pending patents, trademarks, copyrights, trade secrets, research materials, technical information, inventions, test data, know-how, product efficacy and safety data.

Monitoring Trustee: one or more natural or legal person(s), independent from the Parties, approved by the Commission and appointed by Novartis, and who has the duty to monitor the Parties' compliance with the conditions and obligations attached to the Decision.

Parties: Novartis AG and Hexal AG referred to collectively.

Purchaser: the one or more entities approved by the Commission as acquirer of the Divestment Business in accordance with the criteria set out in **Section D**.

Trustee(s): the Monitoring Trustee and the Divestiture Trustee.

Trustee Divestiture Period: the period of [...] months from the end of the First Divestiture Period or the date of appointment of the Divestiture Trustee whichever is the later.

Trustee Mandate: a document agreed by the Trustee and Novartis and submitted to the Commission for its prior approval before signature, by which Novartis appoints a Trustee and sets out the duties and obligations of the signing parties, in accordance with the Commitments.

Novartis: Novartis AG, Lichtstraße 35, CH-4002 Basel, Switzerland.

Hexal: Hexal AG, Industriestraße 25, D-83607 Holzkirchen, Germany.

Work Plan: a detailed plan submitted to the Commission for approval, describing how the Trustee intends to carry out its duties and obligations under the Commitments.

SECTION B: THE DIVESTMENT BUSINESS

1. In order to restore effective competition, Novartis commits to divest, or procure the divestiture, of the Divestment Businesses as defined in this Section and Schedules I to III hereto by the end of the First Divestiture Period as a viable going concern to a purchaser, on terms approved by the Commission in accordance with the procedure described in **Section D, paragraph 2**. These divestitures will remove the entire overlap and transfer Hexal's full market position in the area of H4A in Poland and M2A (OTC) in Germany, and significantly decrease or remove the overlap in the area of M4A in Denmark. To carry out the divestiture, Novartis commits to find a purchaser and to enter into a Divestment Agreement within the First Divestiture Period, and to close the Divestment Agreement within a period not exceeding 3 months after the approval of the Purchaser and the Divestment Agreement by the Commission. If Novartis has not entered into such an agreement before the end of the First Divestiture Period, Novartis shall grant the Divestiture Trustee an exclusive mandate to sell the Divestment Business in accordance with the procedure described in **Section E, paragraph 2.3**, in the Trustee Divestiture Period.
2. Novartis shall be deemed to have complied with this commitment if, either by the end of the First Divestiture Period or the Trustee Divestiture Period, as the case may be, Novartis has entered into a Divestment Agreement with a Purchaser, and the Commission approves the Purchaser and the Divestment Agreement terms in accordance with the procedure described either in **Section D paragraph 2** or in **Section E, paragraph 2.3**, and if Novartis closes the Divestment Agreement within a period not exceeding [...] months after the approval of the Purchaser and the Divestment Agreement by the Commission and transfers all the Assets to the Purchaser at Closing or within an agreed period post-Closing.
3. In order to maintain the structural effects of the Commitments, the Parties shall, for a period of ten years after the Effective Date, not acquire direct or indirect influence

over the whole or part of the Divestment Business, unless the Commission has previously found that the structure of the market has changed to such an extent that the absence of influence over the Divestment Business is no longer necessary to render the proposed concentration compatible with the common market.

4. The Divestment Businesses, described in more detail in Schedules I to III shall include all:
 - (a) rights to tangible and intangible assets (including Intellectual Property Rights), be it by transfer or licensing upon terms acceptable to the Commission and subject to the Commission's prior approval, which contribute to the current operation or may be necessary to ensure the viability, marketability and competitiveness of the Divestment Business;
 - (b) licences, permits and authorisations issued by any governmental organisation for the benefit of the Divestment Business;
 - (c) contracts, agreements, leases, commitments and understandings of the Divestment Business;
 - (d) all customer, credit, other records and documentations in whatever format they may be held, specific to the Divestment Business; and
 - (e) R&D relating to new indications, new formulations and/or variations of the products which are part of the Divestment Business.
5. All authorisations referred to in **paragraph 4(b)** above can be transferred to the Purchaser without the consent, notation, waiver or approval of a third person. In case an authorisation for which consent, notation, waiver or approval of a third person becomes necessary for the divestment of the Divestment Business, the Parties shall use their best endeavours to obtain such consent, notation, waiver or approval.
6. For the avoidance of doubt, the Divestment Businesses shall, not include:
 - (a) Intellectual Property Rights which do not contribute to the current operation or may not be necessary to ensure the viability, marketability and competitiveness of the Divestment Business;
 - (b) the Novartis, Sandoz, Hexal and 1A Farma names and logos in any form;
 - (c) books and records required to be retained pursuant to any statute, rule, regulation or ordinance, provided that copies of such documents necessary for the Divestment Business shall be provided to the Purchaser, upon request; and

- (d) general books of account and books of original entry that comprise the Parties' or an Affiliated Undertaking's permanent accounting or tax records provided that copies of such documents necessary for the Divestment Business shall be provided to the Purchaser, upon request.

SECTION C: RELATED COMMITMENTS

1. Preservation of Viability, Marketability and Competitiveness

Novartis shall use its best endeavours to preserve the economic viability, marketability and competitiveness of the Divestment Businesses from the Effective Date until Closing, in accordance with good business practice. In particular, Novartis undertakes:

- (a) not to carry out any act upon its own authority that might have an adverse impact on the value, management, viability, marketability or competitiveness of the Divestment Businesses or that might alter the nature and/or scope of its activity, the industrial, commercial strategy or investment policy of the Divestment Businesses; and
- (b) to make available the resources necessary for the preservation and development of the Divestment Businesses, on the basis and in continuation of existing business plans until Closing and the full and final transfer of any Assets post-Closing has taken place.

2. Hold-Separate Obligations of the Parties

- 2.1. The Parties commit, from the Effective Date until Closing and the full and final transfer of any Assets post-Closing has taken place, to keep the Divestment Businesses separate from their retained businesses.
- 2.2. Until Closing and the full and final transfer of any Assets post-Closing has taken place, Novartis shall assist the Monitoring Trustee in ensuring that the Divestment Businesses are managed separately from the businesses it is retaining.

3. Ring-fencing

- 3.1. The Parties shall implement all necessary measures to ensure that they do not, after the Effective Date, obtain any business secrets, know-how, commercial information, or any other information of a confidential or proprietary nature relating to the Divestment Businesses. In particular, the participation of the Divestment Businesses in a central information technology network shall be severed to the extent possible,

without compromising the viability marketability or competitiveness of the Divestment Businesses.

- 3.2. Novartis may obtain information relating to the Divestment Businesses, which is reasonably necessary for the divestment of the Divestment Businesses or whose disclosure to Novartis is required by law. Such information necessary for the divestment of the Divestment Business shall be made available only to pre-designated named personnel (including outside advisors) involved in the divestiture process, who shall be under a duty to maintain the confidentiality of such information and to use the same solely for divestiture purposes.

4. Due Diligence

In order to enable potential purchasers to carry out a reasonable due diligence of the Divestment Businesses, Novartis shall, subject to customary confidentiality assurances and dependent on the stage of the divestment process, provide to potential purchasers sufficient time to consult all information necessary to enable the potential purchaser to assess the nature, scope, value, management, viability, marketability and competitiveness of the Divestment Businesses.

5. Reporting

- 5.1. Novartis shall submit written reports in the English language on potential purchasers of the Divestment Businesses and developments in the negotiations with such potential purchasers to the Commission and the Monitoring Trustee no later than ten (10) calendar days after the end of every month following the Effective Date (or otherwise at the Commission's request); however, where this date falls on a day that is not a working day as defined under the Merger Regulation, such written reports will be due on the following working day as defined under the terms of the Merger Regulation.
- 5.2. Novartis shall inform the Commission and the Monitoring Trustee on the preparation of any data room documentation, information memorandum, and the due diligence procedure and shall submit a copy of any information memorandum to the Commission and the Monitoring Trustee for their prior approval before sending the memorandum out to potential purchasers.

SECTION D: THE PURCHASER

1. The Purchaser, in order to be approved by the Commission, must:
 - (a) be independent of and unconnected to the Parties;
 - (b) have the financial resources, proven expertise and incentive to maintain and develop the Divestment Business as a viable and active competitive force in competition with the Parties and other competitors; and
 - (c) neither be likely to create, in the light of the information available to the Commission, prima facie competition concerns nor give rise to a risk that the implementation of the Commitments will be delayed.

(Hereinafter referred to as the “*Purchaser Requirements*”).

2. The Closing of the Divestment Agreement(s) shall be conditional on the Commission’s prior approval of the purchaser and the Divestment Agreement. When Novartis and/or the Divestiture Trustee, as the case may be, have reached an agreement with a purchaser, it shall submit a fully documented and reasoned proposal, including a copy of the Divestment Agreement(s), to the Commission and the Monitoring Trustee. Novartis and/or the Divestiture Trustee must be able to demonstrate to the Commission that the proposed purchaser meets the Purchaser Requirements and that the Divestment Businesses are being sold in a manner consistent with the Commitments. For the approval, the Commission shall verify that the proposed purchaser fulfils the Purchaser Requirements and that the Divestment Businesses are being sold in a manner consistent with the Commitments. The Commission may approve the divestment of the Divestment Businesses without one or more Assets in whole or in parts , if this does not affect the viability, marketability and competitiveness of the Divestment Business after the sale, taking account of the proposed purchaser.

SECTION E: TRUSTEE

1. Appointment Procedure

1.1. Novartis shall appoint a Monitoring Trustee to carry out the functions specified in the Commitments for a Monitoring Trustee. If Novartis has not entered into a Divestment Agreement one month before the end of the First Divestiture Period or if the Commission has rejected a purchaser proposed by Novartis, Novartis shall without delay appoint a Divestiture Trustee to carry out the functions specified in the Commitments for a Divestiture Trustee. The appointment of the Divestiture Trustee shall take effect upon the commencement of the Trustee Divestiture Period.

1.2. The Trustee shall be independent of the Parties, possess the necessary professional experience, qualifications and resources to carry out its mandate, and shall neither be nor become exposed to a conflict of interest. The Trustee shall be remunerated by the Parties in a way that does not impede the independent and effective fulfillment of its mandate. In particular, where the remuneration package of a Divestiture Trustee includes a success premium linked to the final sale value of the Divestment Business, the fee shall also be linked to a divestiture within the Trustee Divestiture Period.

1.3. Proposal by the Parties

No later than one week after the Effective Date, Novartis shall submit to the Commission for approval, a list of one or more persons whom Novartis proposes to appoint as Monitoring Trustee. No later than one month before the end of the First Divestiture Period, Novartis shall submit to the Commission for approval, a list of one or more persons whom Novartis proposes to appoint as Divestiture Trustee. The proposal shall contain sufficient information for the Commission to verify that the proposed Trustee fulfills the requirements set out in **paragraph 1.2** above and shall include:

- (a) full terms of the proposed Trustee Mandate, which shall include all provisions necessary to enable the Trustee to fulfill its functions under these Commitments;
- (b) an outline of a Work Plan which describes how the Trustee intends to carry out its tasks;
- (c) an indication of whether the proposed Trustee is to act as both Monitoring Trustee and Divestiture Trustee or whether different Trustees are proposed for the two functions.

1.4. Approval or rejection by the Commission

The Commission shall have the discretion to approve or reject the proposed Trustee(s) and to approve the proposed Trustee Mandate and/or Work Plan subject to any modifications the Commission deems necessary for the Trustee to fulfill its functions effectively. If only one individual or institution is approved, Novartis shall appoint or cause to be appointed, the individual or institution concerned as Trustee, in accordance with the Trustee Mandate and Work Plan approved by the Commission. If more than one individual or institution is approved, Novartis shall be free to choose the Trustee to be appointed from among the individuals or institutions approved. The Trustee shall be appointed within one week of the Commission's approval, in accordance with the Trustee Mandate and Work Plan approved by the Commission. The Trustee Mandate and Work Plan will be signed in triplicate and one original will be forwarded without delay to the Commission.

1.5. New proposal by the Parties

If all the proposed Trustees are rejected, Novartis shall submit the names of at least two more individuals or institutions within one week of being informed of the rejection, in accordance with the requirements and the procedure set out in **paragraphs 1.3 and 1.4** above.

1.6. Trustee nominated by the Commission

If the Commission rejects all further proposed Trustees, the Commission shall nominate a Trustee, whom Novartis shall appoint, or cause to be appointed, in accordance with a Trustee Mandate and Work Plan approved by the Commission. The Trustee Mandate and Work Plan will be signed in triplicate and one original will be forwarded without delay to the Commission.

2. Functions of the Trustee

2.1. The Trustee shall assume its specified duties in order to ensure compliance with the Commitments. The Commission may, on its own initiative or at the request of the Trustee or Novartis, give any orders or instructions to the Trustee in order to ensure compliance with the conditions and obligations attached to the Decision.

2.2. Duties and obligations of the Monitoring Trustee

Following its appointment, the Monitoring Trustee shall:

- (a) oversee the ongoing management of the Divestment Businesses with a view to ensuring its continued economic viability, marketability and competitiveness and monitor compliance by the Parties with the conditions and obligations attached to the Decision. To that end the Monitoring Trustee shall:

- (i) monitor the preservation of the economic viability, marketability and competitiveness of the Divestment Businesses and the keeping separate of the Divestment Businesses from the businesses retained by the Parties, including, where necessary, the determination of the managerial decisions required to that end, in accordance with **Section C, paragraphs 1 and 2** of the Commitments;
 - (ii) in consultation with the Parties, determine all necessary measures to ensure that the Parties do not, after the Effective Date, obtain any business secrets, know-how, commercial information, or any other information of a confidential or proprietary nature relating to the Divestment Businesses, in particular strive for the severing of the Divestment Business' participation in a central information technology network to the extent possible, without compromising the viability marketability or competitiveness of the Divestment Business;
 - (iii) oversee the ring-fencing measures put in place to enable any business secrets, know-how, commercial information, or any other information of a confidential or proprietary nature relating to the Divestment Businesses to be disclosed to Novartis to the extent such disclosure is reasonably necessary to allow Novartis to carry out the divestiture or to the extent that its disclosure to Novartis is required by law;
 - (iv) monitor any necessary splitting of Assets that may be shared by the Divestment Businesses and the Parties' retained businesses.
- (b) assume any other functions assigned to the Monitoring Trustee under the conditions and obligations attached to the Decision, the Trustee Mandate, Work Plan and/or as instructed by the Commission from time to time;
 - (c) propose to Novartis such measures as the Monitoring Trustee considers necessary to ensure Novartis's compliance with the conditions and obligations attached to the Decision, in particular the maintenance of the full economic viability, marketability or competitiveness of the Divestment Businesses, the separation and holding separate of the Divestment Businesses and the non-disclosure of competitively sensitive information;
 - (d) review and assess potential purchasers as well as the progress of the divestiture process and verify that, dependent on the stage of the divestiture process, potential purchasers receive sufficient information relating to the Divestment Businesses and in particular by reviewing any data room documentation and information memorandum and overseeing the due diligence process, if applicable;

- (e) provide to the Commission, sending Novartis a non-confidential copy at the same time, a written report within fifteen (15) calendar days after the end of every month; however, where this date is not a working day within the meaning of the Merger Regulation, such written reports will be due on the following working day as defined under the terms of that Regulation. The report shall cover the operation and management of the Divestment Business to enable the Commission to assess whether the business is held in a manner consistent with the Commitments and the progress of the divestiture process as well as potential purchasers. In addition to these reports, the Monitoring Trustee shall promptly report in writing to the Commission, sending Novartis a non-confidential copy at the same time, if it concludes on reasonable grounds that Novartis is failing to comply with these Commitments;
- (f) within one week after receipt of the documented proposal referred to in **Section D paragraph 2**, submit to the Commission a reasoned opinion on whether the proposed purchaser fulfils the Purchaser Requirements and whether the Divestment Business is sold in a manner consistent with the conditions and obligations attached to the Decision, in particular, if relevant, whether the sale of the Divestment Business without one or more Assets affects the viability, marketability and competitiveness of the Divestment Business, taking account of the proposed purchaser.

2.3. Duties and obligations of the Divestiture Trustee

- (a) Within the Trustee Divestiture Period, the Divestiture Trustee shall [...] negotiate the Divestment Agreement as set out above with a Purchaser, subject to the Commission's prior approval of that Purchaser and the Divestment Agreement in accordance with the procedure laid down in **Section D paragraph 2**. The Divestiture Trustee shall include in the Divestment Agreement such terms and conditions as it considers appropriate for an expedient agreement. In particular, the Divestiture Trustee may include in the Divestment Agreement such provisions as are reasonably required to effect the agreement. The Divestiture Trustee shall protect the legitimate interests of Novartis, subject to the Parties' unconditional obligation to divest in the Trustee Divestiture Period.
- (b) In the Trustee Divestiture Period (or otherwise at the Commission's request), the Divestiture Trustee shall provide the Commission with a comprehensive monthly report written in the English language on the progress of the divestiture process. Such reports shall be submitted within fifteen (15) calendar days after the end of every month with a simultaneous copy to the Monitoring Trustee and a non- confidential copy to Novartis.

3. Duties and obligations of the Parties

- 3.1. The Parties shall provide and shall cause its advisors to provide the Trustee with all such assistance and information, including copies of all relevant documents, as the Trustee may reasonably require in performance of its tasks. In addition, the Trustee shall have full and complete access to any of the Parties' or the Divestment Business' books, records, documents, personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments. The Parties and the Divestment Business shall make available to the Trustee offices on their premises and a representative of the Parties shall be available for meetings in order to provide the Trustee with all information necessary for the performance of its tasks.
- 3.2. The Parties shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of the Divestment Business. This shall include all administrative support functions relating to the Divestment Business, which are currently carried out at headquarters level. The Parties shall provide and shall cause their advisors to provide the Monitoring Trustee with access to the information submitted to potential purchasers, in particular, to any data room documentation, information memorandum and all other information granted to potential purchasers in the due diligence procedure. The Parties shall inform the Monitoring Trustee on potential purchasers, submit a list of potential purchasers, and keep the Monitoring Trustee informed of all developments in the divestment process.
- 3.3. The Parties shall grant and/or procure Affiliated Undertakings to grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee to effect the Divestment Agreement, the Closing and transfer of the Assets as well as all actions and declarations which the Divestiture Trustee considers necessary or appropriate to achieve the divestment and the Closing, and transfer of the Assets including the appointment of advisors to assist with the process of concluding a Divestment Agreement. Upon request of the Divestiture Trustee, Novartis shall cause the documents required for effecting the divestment, the Closing and transfer of the Assets to be duly executed.
- 3.4. Novartis shall indemnify the Trustee and its employees, agents or advisors (each an "*Indemnified Party*") and hold each Indemnified Party harmless against any liabilities arising out of the performance of the Trustee's duties under the Commitments, except to the extent that such liabilities result from the wilful default, recklessness, gross negligence or bad faith of the Trustee, its employees, agents or advisors.

- 3.5. At the expense of Novartis, the Trustee may appoint advisors (in particular, for corporate finance or legal advice), subject to Novartis's approval (this approval not to be unreasonably withheld or delayed) if the Trustee considers the appointment of such advisors necessary or appropriate for the performance of its duties and obligations under the Trustee Mandate, provided that any fees and other expenses incurred by the Trustee are reasonable. Should Novartis refuse to approve the advisors proposed by the Trustee the Commission may approve the appointment of such advisors instead, after having heard Novartis. Only the Trustee shall be entitled to issue instructions to the advisors. In the Trustee Divestiture Period, the Divestiture Trustee may use advisors who served Novartis during the First Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient divestment.
4. Replacement, discharge and reappointment of the Trustee
- 4.1. If the Trustee ceases to perform its functions under the Commitments or for any other good cause, including the exposure of the Trustee to a conflict of interest:
- (a) the Commission may, after hearing the Trustee, require Novartis to replace the Trustee; or
 - (b) Novartis, with the prior approval of the Commission, may replace the Trustee.
- 4.2. If the Trustee is removed according to **paragraph 4.1**, the Trustee may be required to continue in its function until a new Trustee is in place to whom the Trustee has effected a full hand over of all relevant information. The new Trustee shall be appointed in accordance with the procedure referred to in **paragraphs 1.3 and 1.4** above.
- 4.3. Beside the removal according to **paragraph 4.1**, the Trustee shall cease to act as Trustee only after the Commission has discharged it from its duties after all the Commitments with which the Trustee has been entrusted have been implemented. However, the Commission may at any time require the reappointment of the Monitoring Trustee if it subsequently appears that the Commitments might not have been fully and properly implemented.

SECTION F: THE REVIEW CLAUSE

1. The Commission may, where appropriate, in response to a request from Novartis showing good cause and accompanied by a report from the Trustee:
- (a) grant an extension of the time periods foreseen in the Commitments; or

- (b) waive, modify or substitute, in exceptional circumstances, one or more of the undertakings in these Commitments.
2. Where Novartis seeks an extension of a time period, it shall submit a request to the Commission no later than one month before the expiry of that period, showing good cause. Only in exceptional circumstances shall Novartis be entitled to request an extension within the last month of any period.
3. In case of a material change of circumstances, Novartis reserves its rights under Community law to request the Commission to review in whole or in part any specific undertakings relating to these Commitments.

Signed in Basel on May 25, 2005

For and on behalf of **Novartis AG**

[...]

Signed in Holzkirchen on May 25, 2005

For and on behalf of **Hexal AG**

[...]

SCHEDULE I

DIVESTITURE OF CALCIHEXAL IN POLAND

1. Novartis offers to procure the divestiture of the rights in the sale and marketing of Calcihexal (H4A) in Poland. These rights include:
 - a) The marketing authorization for Calcihexal in Poland. Novartis will submit the necessary notice of the transfer to the regulatory authority, if required.
 - b) All relevant dossiers relating to the marketing authorization as far as available to the current marketing authorization holder.
 - c) An irrevocable, assignable and sub-licensable exclusive license, including Intellectual Property Rights, to manufacture, use and sell existing formulations of Calcihexal by the Purchaser for the indications covered by the marketing authorization.
 - d) The exclusive right to use the Calcihexal trademark in Poland for the products covered by the marketing authorization. However, if the Polish regulatory authorities reject the transfer of the trademark to the Purchaser, this trademark may be used with a suffix or prefix indicating the new marketing authorization holder's name ("branding plus"). Only if branding plus is not acceptable to the Polish regulatory authorities, the Parties will, at their expense and in full consultation with the Purchaser and subject to the Commission's prior approval of the proposed modalities, re-brand the product prior to divestiture and grant the Purchaser the exclusive right to use the new brand after the transfer of the marketing authorization. If such re-branding is not possible without affecting the viability, marketability and/or competitiveness of the Divested Business, the Parties will revert to the Commission under **Section F paragraphs 1(b) and 3** of these Commitments. In the case of branding plus or re-branding, the Parties may not make use of the Calcihexal brand in Poland without first obtaining the Commission's prior approval under **Section F paragraph 3**.
 - e) All relevant data, books and records on existing customers of Calcihexal in Poland.
2. At the option of the Purchaser, Novartis will enter into a supply or toll-manufacturing agreement with the Purchaser on a "cost plus" basis, for the non-exclusive supply or toll manufacturing of the existing formulations of Calcihexal in Poland. The duration of such an agreement will not exceed a term of [...] years. The terms of the "cost plus" basis shall be agreed between Novartis and the Purchaser, subject to the Commission's approval, to cover the Parties' costs and expenses

directly or indirectly related to their manufacture and supply plus an overhead of no more than [...] %.

SCHEDULE II

DIVESTITURE OF TOPICAL DICALAC IN GERMANY

1. Novartis offers to procure the divestiture of the rights in the sale and marketing of topical Dicalac in the variations “Dicalac Schmerzgel” and “Dicalac – 5% Gel” (hereinafter “Dicalac”) in Germany. These rights include:
 - a) The marketing authorizations for Dicalac in Germany. Novartis will submit the necessary notices of the transfer to the regulatory authority, if required.
 - b) All relevant dossiers relating to the marketing authorizations as far as available to the current marketing authorization holder.
 - c) An irrevocable, assignable and sub-licensable exclusive license, including Intellectual Property Rights, to manufacture, use and sell existing formulations of Dicalac by the Purchaser for the indications covered by the marketing authorizations.
 - d) The exclusive right to use the trademarks “Dicalac” and “Dicalac Schmerzgel” in Germany for the products covered by the marketing authorizations. However, the trademarks may only be used with a suffix or prefix indicating the new marketing authorization holder’s name (“branding plus”).
 - e) All relevant data, books and records on existing customers of Dicalac in Germany.
2. At the option of the purchaser, Novartis will enter into a supply or toll-manufacturing agreement with the Purchaser, on a “cost plus” basis, for the non-exclusive supply or toll manufacturing of the existing formulations of Dicalac in Germany. The duration of such an agreement will not exceed a term of [...] years. The terms of the “cost plus” basis shall be agreed between Novartis and the Purchaser, subject to the Commission’s approval, to cover the Parties’ costs and expenses directly or indirectly related to their manufacture and supply plus an overhead of no more than [...] %.

SCHEDULE III

DIVESTITURE OF APURIN IN DENMARK

1. Novartis offers to procure the divestiture of the rights in the sale and marketing of Hexal's *Apurin* in Denmark. These rights include:
 - a) The marketing authorization for *Apurin* in Denmark. Novartis will submit the necessary notice of the transfer to the regulatory authority, if required.
 - b) All relevant dossiers relating to the marketing authorization as far as available to the current marketing authorization holder.
 - c) An irrevocable, assignable and sub-licensable exclusive license, including Intellectual Property Rights, to manufacture, use and sell existing formulations of *Apurin* by the Purchaser for the indications covered by the marketing authorization.
 - d) The exclusive right to use the *Apurin* trademarks in Denmark for the products covered by the marketing authorization.
 - e) All relevant data, books and records on existing customers of *Apurin* in Denmark.
2. At the option of the purchaser, Novartis will enter into a supply or toll-manufacturing agreement with the Purchaser, on a "cost plus" basis, for the non-exclusive supply or toll manufacturing of the existing formulations of *Apurin* in Denmark. The duration of such an agreement will not exceed a term of [...] years. The terms of the "cost plus" basis shall be agreed between Novartis and the Purchaser, subject to the Commission's approval, to cover the Parties' costs and expenses directly or indirectly related to their manufacture and supply plus an overhead of no more than [...] %.
3. At the request of the Purchaser, the Parties will also offer the divestiture of Hexal's *Allopurinol* under the conditions set out for the divestiture of *Apurin* under **paragraphs 1 and 2** above.