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## **Meeting Challenges of the Pharmaceutical Industry**

### **Today and Tomorrow**

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## **Introduction: Defining Bosch in the Marketplace**

Welcome to Bosch Packaging Technology's press conference. In the pharma industry we provide complete solutions from processing to packaging. We also provide the expertise enabling our customers to assemble complete automated systems ideally suit their needs. The new technologies Bosch is introducing at Achema help our customers meet many of the challenges and trends in the pharmaceutical industry today. Our consistent investment and growth in strategic arenas is leading to better technology and service for our customers worldwide to meet the demands of these trends and, ultimately, succeed.

Following the successful integration of the Sigpack companies over the last two years, sales from the Packaging Technology Division grew to 927 million Euros. The growth is strongly driven by the business field ATMO, which delivers assembly systems and special machinery for other divisions of Bosch. In 2005 the sales in the core business of packaging accounted for 541 million Euros.

Bosch Packaging Technology delivers reliable solutions for various products and packaging styles in different industries. The major part of the business exists in the pharmaceutical industry. Despite of the decreased sales volume in 2005 the Pharma business, with a share of 44 % order income, is even gaining importance in our portfolio. Solutions for the food industry account for 30 % of the total sales. Bosch also provides full line processing and packaging solutions for the confectionery industry which account for 22 % of the sales. The remaining 4 % come from sales to cosmetics, chemicals and non-food product segments.

As a global player in our industry, we generated 87 % of our sales outside of Germany and 55 % of the business is done outside of Western Europe. Although the overall sales volume is lower than in 2004, the worldwide spread of our activities is stable. Just the share of sales in Germany was stronger in 2005 which was compensated in the worldwide mix.

### **Industry Trends: Global Markets / Changing Dynamics**

In 2005 the total pharmaceutical market grew by 7% to 500 billion Euros. Emerging markets such as China, Russia, Turkey and Korea had double digit growth, contributing significantly to this large growth rate.

The large growth in the developing markets is based on the significant growth of the gross domestic product (GDP) growth which helps to finance improvements in the healthcare systems. Higher personal incomes also allow more people to purchase medicines. For the future, markets in China, India, and Brazil will provide strong growth opportunities for the industry based on the expanding pharmaceutical manufacturing capabilities and also based on the increased regulations towards product quality and security.

In terms of packaging, there is robust growth ahead for this sector. The global pharmaceutical and healthcare packaging market will grow with a compound annual growth rate (CAGR) of 6.2 % from around 16 billion Euros in 2005 to 21 billion Euros in 2009. With approximately 34 % of the share, North America is still the largest market, followed by Western Europe with 29 % and Asia with 24 %. Eastern Europe's share is relatively low at 4.5 % but expected to increase above average to 5.3 % in 2009.

The pharmaceutical packaging technology market for new machines accounted for around 2.7 billion Euros in 2005 with Bosch having a share of approximately 9 %. The market is estimated to grow by 4.3 % until 2009.

Currently the pharmaceutical industry is facing major changes since the rate of drug discovery is expected to decrease significantly. Beside a decreasing rate of new drugs launched on the market, pharmaceutical companies expect R&D costs to increase significantly. The challenge for the future will therefore be to meet growth expectations while facing a declining product pipeline.

Another ongoing trend is the increasing heterogeneity in customer requirements which will lead to higher complexity in product handling. This will open up new opportunities for suppliers to this industry. The introduction of substituting generic products and with this increasing buying power of the end-user market will lead to increasing rivalry amongst established pharmaceutical producers.

These trends will bring significant cost pressure to manufacturers who will need to streamline their operations and bring greater efficiency to their operations. Today, the overall efficiency of such operations is still low compared to some food industries so there is room for technology to help fill the gap and help the industry meet the cost demands of these growing trends.

Higher machine throughput, increased automation, multi-shift operation and greater flexibility of equipment with regard to different packaging formats and/or materials are just some of

the features pharmaceutical manufacturers are looking for. In addition, preventive maintenance and process optimization to increase production efficiency are also needed by the industry to fully take advantage of the industries changing needs.

To be successful in today's business environment, pharmaceutical companies need to be innovative in all aspects of their operation from processing to packaging to marketing. Technology can help but only in tandem with expertise in customizing and integrating these technologies. It is this combination of technology and expertise that Bosch is showcasing here at Achema. Specific examples of trends illustrate this point:

**Trend: Syringes**

The trend toward pre-filled syringes for vaccines, heparin, cardiovascular products and new biotech drugs, provides a good example of how Bosch offers a wide range of expertise and technologies providing an efficient, safe, and reliable processing and packaging solution. In the end, this allows our customers to deliver a safer and easier to use product to end users.

“Ready-to-use” syringes are increasingly preferred by medical personnel for delivering precise dosage of medication safely and efficiently. To supply this market, pre-sterilized syringes are delivered in sealed plastic containers or tubs direct to the filling and packaging operation thus eliminating the need for cleaning and heat sterilization. Increasing numbers of suppliers of pre-sterilized, ready-to-fill syringes have given this segment stronger market shares compared to bulk syringes which need to be processed prior to filling.

Bosch began serving the syringe market over 20 years ago and has steadily enhanced its offering to the industry since. At Achema we are presenting new developments for the filling of pre-sterilized syringes centered around the FXS 5100 filling- and sealing machine.

The new Bosch FXS 5100, capable of filling and sealing up to 30,000 syringes an hour, meets market demands with a fully automatic processing solution for filling and sealing syringes in high capacities and with optimal security. Based on proven Bosch syringe transport technology, the FXS 5100 features a fully automatic in-line weight inspection and integrated isolator unit offering users a compact and easy to use machine with optimal process security.

In addition, space saving and economy in Bosch's new system extends to the process before syringes are actually filled. For example, an automated system for opening tubs in a sterile isolator unit minimizes particle dispersion. This technology was developed through Bosch research and through collaboration with knowledgeable partners offering the market a safe and economic solution.

So here we see at Achema, how Bosch is delivering not just a packaging machine, but an entire system that brings greater automation and efficiency to meet a growing industry trend.

**Trend: Delivering Efficient OTC Convenience**

Trends in delivering greater convenience, safety and usability also extend to patient administered pharmaceuticals. Bosch works closely with its customers to ensure that they can supply the market for patient administered medication efficiently. For

example Sigpack Systems, a Bosch Packaging Technology company, worked with Warner Chilcott, a U.S. based pharmaceutical company focused on women's healthcare, to create a customized blister packaging system. With a production speed of more than 170 packages per minute contraceptive pill blisters are hermetically sealed with an aluminum foil. The blister package includes a plastic wallet as blister envelop, a desiccant and a small leaflet. All packaging components are automatically handled at the in-feed chain of the flow wrapping machine with integrated control units for supply verification.

Here at Achema, this customized packaging solution is demonstrated with an additional robotic solution for product handling and an integrated topper platform for end of line packaging.

Streamlining process and maximizing efficiency, as in the Warner Chilcott example, are all areas in which Bosch excels. However, we also offer broader solutions to customers that help better market products through visual appeal and great usability.

For over the counter (OTC) products, marketing is more geared toward the visual appeal, convenience, and usability as key drivers in our product development. Wallets are a good example of a packaging solution that adds convenience to prescription and OTC pharma products. Consumers find them easy to use and incorporate into their daily lives and they can be vital in creating an overall positive experience between a brand and a patient. Also wallets offer some advantages in anti-counterfeiting since they are difficult to duplicate. There are also technologies that incorporate electronics and radio frequency identifica-

tion (RFID) into wallets to further assist patients in taking the correct dosage of medication at the correct time.

Here at Achema, the Pharma Solid unit of Bosch is introducing the new Smart Wallet: an easy to manufacture wallet style package for solid pharmaceuticals with a CUT130SW intermittent motion cartoning machine.

Smart Wallet offers pharmaceutical manufacturers a wallet solution that is convenient, easy to use, tamper evident, reclosable and cost-effective. The equipment required to create Smart Wallet has a smaller footprint and requires a smaller overall investment in comparison to a conventional wallet packaging machine.

The key to Smart Wallet's efficiency is the pre-glued outer sleeve of the wallet, which can be erected and loaded with the blister on a conventional cartoning machine at production speeds of up to 300 wallets per minute. Smart Wallet cartoning machines can also be built to produce both wallets and conventional folding boxes. This is ideal for a dual strategy of production allowing better utilization of the line, particularly if only a smaller part of the production volume is in a wallet. Again, we are helping our customers meet a growing trend, efficiently, and effectively.

### **Trend: Process Automation**

Packaging in the pharma industry is very often closely related to processing and the automation of processing.

An arena that emphasizes this point is in injectable vials with stable growth for liquid and powder parenteral substances. Re-

cently, the industry has trended toward requiring more formulations for freeze drying which is more stable compared to liquids. The worldwide increasing demand for human insulin has led to the development of cartridge lines with very high outputs for multi-shift operations. The demand for barrier technology for aseptic filling line, isolators and for containments has been significantly growing due to Food and Drug Administration (FDA) guidelines for aseptic manufacturing which recommends the use of such concepts.

At Achema, we're displaying aseptic filling solutions as well as advanced isolator technologies that automate testing to ensure efficiency as well as compliance. Working with customers to integrate a wide range of equipment: from isolator technology to filling equipment, the industry can meet these trends efficiently and safely.

Bosch's reach through expertise and technology in processing is highlighted in many applications that integrate Process Analytical Technology or PAT. PAT is the FDA's risk-based approach enables high efficiency and quality assurance in pharmaceutical manufacturing by introducing inspection and controlling systems throughout the entire process, called closed loop control. This means that, by using technology, products are checked and adjusted automatically at several steps of the production process. Nothing advances to the next step unless a problem is either fixed or a faulty element is rejected from the system. PAT moves beyond checking and validating quality, to actually providing a way to increase uptime and efficiency.

Bosch offers an array of equipment that allows for effective in-line analysis and control of critical process parameters for filling capsules and liquid pharmaceutical products. For instance,

Bosch Pharma Solid offers a system for the filling of capsules. At several points in the capsule filling process quality parameters are monitored and controlled. In preliminary sorting, capsules of a sub-standard quality are identified and eliminated. Compressed air and vacuum-monitoring units constantly check operating pressure and stop the system before malfunctions arise. A Near Infrared (NIR) system verifies the active ingredient content, and the filling weight is monitored by a check weighing system operating in closed-loop control with the filling system to automatically increase or decrease the powder dosing amount to match the correct specification. Problems are not just identified; they are fixed along the way in a closed loop which identifies faults before they can significantly reduce downtime.

In this area Bosch has already gained some expertise since we have devoted a team currently working with several customers to integrate PAT technology into their filling and processing lines. There are some individual technologies and partnerships that we launched in the past year to specifically address PAT. For example we recently introduced a vision-based particle inspection system from our inspection system company Moeller & Devicon. It incorporates 100% non-contact, non-contaminated inspection which delivers high inspection accuracy in a simplistic and safe way exceeding the performance delivered by other systems in the market. This technology is ideal for inspecting challenging products such as suspensions. With technologies that were developed in accordance with the FDA's PAT initiative Bosch is offering customers to help them take full advantage of PAT.

There are many PAT solutions at our stand here at Achema, but more importantly, there are also experts to answer questions about this important growing trend.

### **Technology Meets Trends**

In conclusion, I would like to say that as a leading supplier to the pharmaceutical industry, Bosch is in a unique position because we offer such a broad range of products and services that cover almost the entire gamut of the industry.

Today's pharmaceutical manufacturer has so much at technology at his or her fingertips to help deliver a safer, higher quality, easier to use product. At the same time, it is vital to have a partner to work with to leverage this technology to the fullest. Bosch can bring together a full spectrum of technology, expertise and services to be an effective partner.

Our new advertising and marketing campaign is based on the tagline: Pharma solutions like you've of never seen before. This both sums up our offering to the industry and answers an important need. The pharma industry needs unprecedented levels of innovation, flexibility and efficiency in order to compete effectively in an increasingly global, cost conscious world. In other words, our customers need solutions they have never seen before to meet industry challenges they have never seen before.