Japan is taking big steps to create outsourcing opportunities for pharmaceutical companies. The bill would permit drug companies to outsource their manufacturing to GMP-compliant firms as certified by the Ministry of Health, Labor, and Welfare (HLW) and FDA. Observers say the bill would also open the Japanese market to US and European firms, which in the past could enter that market in most cases only by partnering with Japanese pharmaceutical companies.

Even if the bill passes, however, the program may take as long as three years to implement, notes Yoshikazu Hayashi, an HLW deputy director. “During that period, many government and ministerial ordinances will be prepared to determine in detail how things will operate,” he says.

Many major pharmaceutical companies seem to be preparing for passage already, and one highly placed source says the outsourcing provision is noncontroversial and is widely supported. “It is like ice melting; it will happen in time.”

The bill is viewed as critical to the health of Japan’s pharmaceutical industry. “In Japan only R&D-oriented companies can survive, and it is important for us to restructure the production division,” notes Seizo Masuda of Takeda, Japan’s largest drug maker. “Under current law, we cannot perform outsourcing from A to Z, but under the proposed bill, we could contract all of our manufacturing and packaging to outside companies.”

US observers see the bill as a big step. “This market has made major strides in aligning itself with international standards for clinical trials processes and in recognizing the need to streamline its process for drug approval,” said Joseph Damond of PhRMA. For US or Japanese start-up companies without local manufacturing facilities, the measure would afford them an opportunity to enter the Japanese market.

M&A update

Galen Holdings PLC (Craigavon, UK) took one more step out of the contract services business by selling its contract clinical packaging business, Clinical Trials Services (CTS), to members of CTS to members of CTS. BLP will become part of Cardinal Health’s Pharmaceutical Technologies and Services (PTS) group, which offers dosage form development and manufacturing, analytical chemistry, and packaging services as well as proprietary drug delivery technologies. PTS recently completed its acquisition of Magellan Laboratories, Inc. (Research Triangle Park, N.C.). With the BLP acquisition, Cardinal is seeking to gain access to decision-makers within sponsor marketing groups, who are drivers of decisions regarding new delivery technologies offered by Cardinal, and to leverage relationships it is building within senior management levels at pharmaceutical companies. BLP services also complement contract sales and distribution services offered by other Cardinal divisions.

Q1 performance

CROs and CMOs started the year strong, but there were a few danger signs on the horizon. Revenues for the 17 companies in the PharmSource sample grew 9.3% overall, but 8 companies had revenue growth of 14% or more. Profits generally climbed faster than revenues.

Still the picture was not totally positive. CROs warned of higher-than-usual cancellation rates and a slowdown in discovery-related spending by sponsors. AAI International (Wilmington, NC), the contract services subsidiary of aalPharma, reported a decline in revenues, and its president was replaced. Omnicare announced that it would not rebuild its Omnicare Pharmaceuticals CMC services group, which was shut down by flooding at its Fort Washington, Pennsylvania, facility last year. PT