IMPORTANCE OF TENDERING AFTER PATENT EXPIRY IN GERMANY

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OBJECTIVES

The loss of market exclusivity is a natural milestone in the lifecycle of a patent-protected pharmaceutical. Once the patent protection for a substance expires, generic equivalents can enter the market and compete with the original brand-name product. As generics typically are sold at substantially lower prices, the companies are challenged to keep their share of the market. A key to managing patent expiry and the impending decline in sales volume and revenue could be entering into *drug discount contracts with German statutory health insurance (SHI) companies*. Those contracts oblige the pharmaceutical companies to grant a discount on the list price. In turn, the health insurers restrict supply to the product to which the contract applies.

METHODS

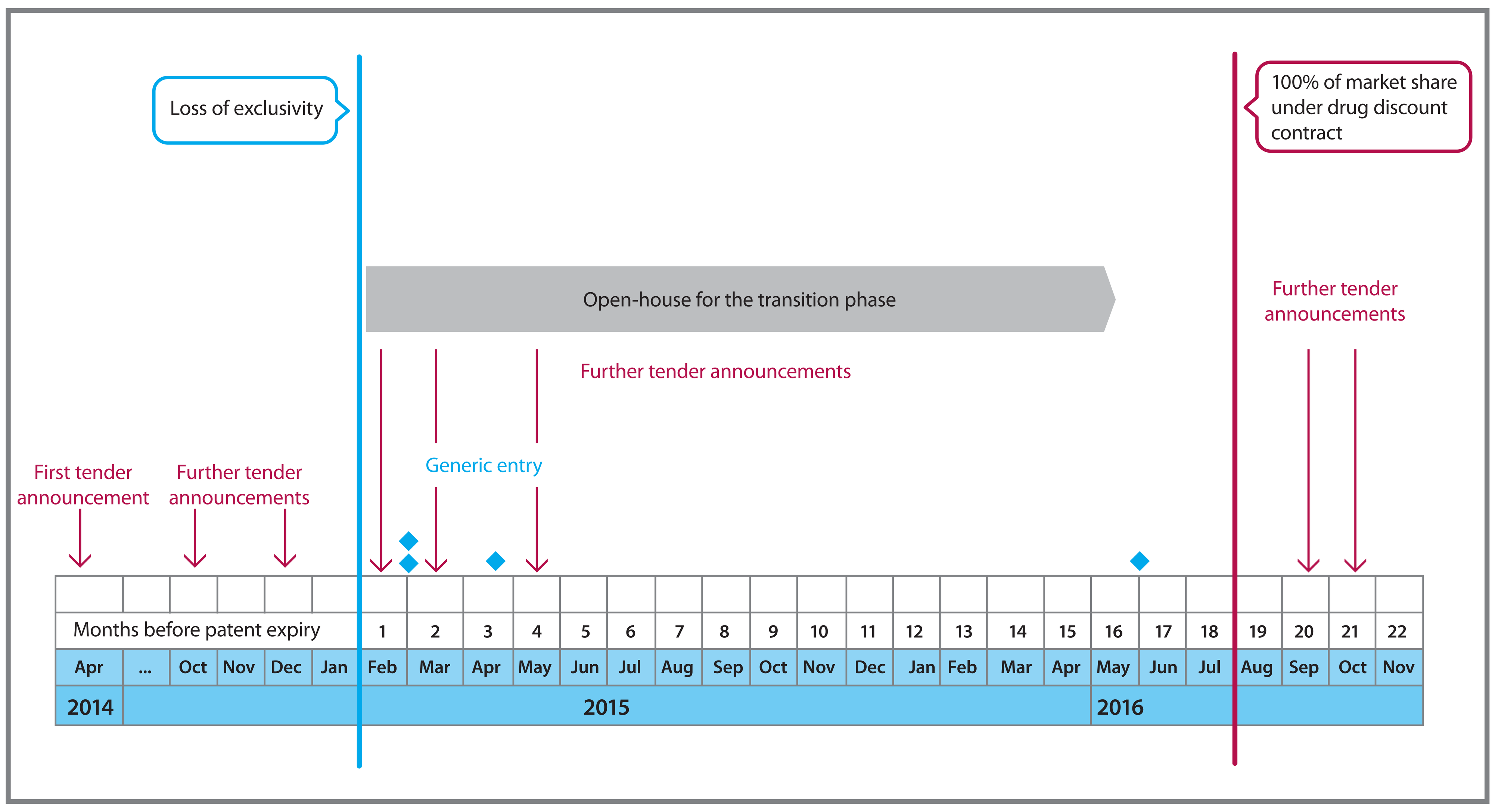
The analysis is based on substances that have lost patent protection in Germany from 2013 to 2016 (n=42). Selected substance markets were analyzed by comparing the tender announcement by health insurers, the tender strategy of manufacturers, and price and volume trends. Key issues are the time of tender announcement and the preferred tender models by health insurers as well as identified strategies of originators.

Types of drug discount contracts in Germany

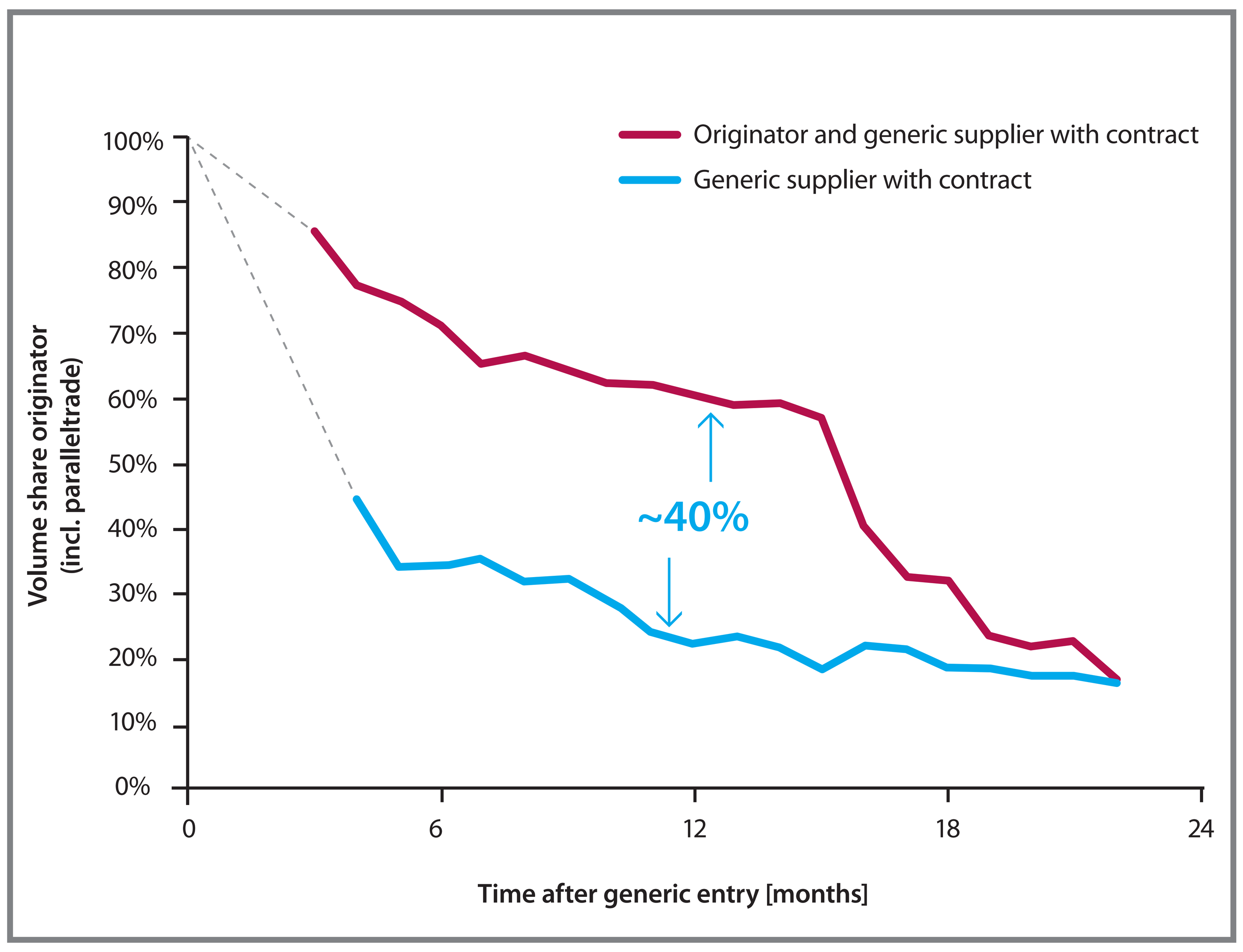
	Open-house models	Exclusive drug discount contracts
Conditions	Identical and not individually negotiable discount agreements (fixed discount)	Exclusivity for selected companies/ importers (one up to 3 companies)
Basic rule	Right of participation for all interested companies/ importers	Tendering in the line with the EU procurement law
Win criteria	- Approval of eligibility requirements - Supply reliability	- Lowest price - Supply reliability
Admission time	Permanent during the contract period	Usually 4 up to 8 weeks after the announcement
Duration	Usually 2 years (maximum)	2 years

RESULTS

Timeline for entry of generics and drug discount contracts (historical illustrative example)



Influence of open-house contracts (example: Sevelamer)



- Frequently, open-house contracts are “bridging contracts” in preparation for exclusive drug discount contracts.
- The tenders for open-house models are often announced **before** patent expiry and generic entry (1 month up to 13 months before loss of exclusivity date).
- The tenders for exclusive drug discount contracts are usually announced **after** patent expiry.
- Statutory health insurance companies offer tender announcements for all examined active substances (n=42).
- In the vast majority of cases generic companies as well as the originator adopt a drug discount contract strategy.

- In case that **only generic suppliers have a contract**, originators are challenged with immediate loss of volume share.
- The participation in drug discount contracts secures a significant higher volume share the originator for a relatively long period of time.
- In this example, there are approximately 40% difference in volume share between the situation in which the **originator and generic suppliers have a contract** and the situation in which **only generic suppliers have a contract**.
- But this protective effect of participation in open-house models decreases over time.

CONCLUSION

- Drug discount contracts are an effective instrument for originators to prevent substitution at the pharmacy and to delay erosion of market share.
- In this context, open-house models are the dominating drug discount contract model after patent expiry.
- The implementation of an effective tender strategy requires early preparation and changes in the business models for concerned pharmaceutical companies.
- But the decision for participation or no participation in general depends on the market volume, number of suppliers and the expected price erosion.

REFERENCES

- Substances that lost patent protection were taken from Schwabe/Paffrath (2016): Arzneiverordnungs-Report 2016.
- Tender announcements and acceptance of bid were taken from “Tenders electronic daily” Supplement zum Amtsblatt der Europäischen Union.

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