

## PURDUE

To:	Purdue Sales Force	From: Andrea Buechel OxyContin Product Manager, Marketing
Number:	38	Date: April 8, 2015

## Authorized Generics for Oxycodone Extended-Release (ER) Q&A Guidance for Oral Discussions

The attached Q&A document is being provided so you are prepared to respond to questions you may receive from your customers regarding generic oxycodone extended-release (ER) entering the marketplace.

On April 1, Teva Pharmaceuticals published a press release announcing they will begin selling Oxycodone Hydrochloride Extended-Release Tablets, CII, the generic form of OxyContin. This document is for training and informational purposes only and is not intended for distribution. Please direct any additional questions to your Manager or Purdue Medical Services at (888) 726-7535.

The information provided should only be used reactively in discussions with healthcare professionals.

This guidance is to address unsolicited questions you may get from HCPs about this subject and should not be used as part of your promotional efforts.

Any unsolicited questions that you cannot answer or that go beyond the information provided in the attached document should be submitted to Purdue Medical Services using a Medical Information Request Form (eMIRF).

Please direct any additional questions to your Manager.



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## Authorized Generics for Oxycodone Extended-Release (ER) Q&A Guidance for Oral Discussions REACTIVE USE ONLY AND NOT FOR DISTRIBUTION

### Guidance for Use by: Sales Field Force (SFF)

This document is intended to be used by SFF in responding to questions they may receive about generic oxycodone extended-release (ER) entering the marketplace. This document is for training and informational purposes only and is not intended for distribution. Please direct any additional questions to your Manager or Purdue Medical Services at (888) 726-7535.

### 1. What is an Authorized Generic?

Authorized generics are prescription drugs produced by or for brand pharmaceutical companies pursuant to the brand's New Drug Application (NDA) and marketed under a generic's label without the use of the brand's trademarks, e.g. OxyContin<sup>®</sup>.

# 2. Are there other companies manufacturing and distributing generic oxycodone ER that are not authorized?

No.

3. When do you anticipate that generic oxycodone ER products will be on the market? When do we anticipate them coming off the market?

The supply will be limited and likely sporadic.

4. What percent of the market will be generic?

We anticipate retaining the vast majority of the current OxyContin market with our brand on an annual basis.

5. What will the pricing be for generic oxycodone ER?

We cannot speculate on how generic manufacturers will price their products.

- 6. When does the last patent on OxyContin expire?
  - The last patent for OxyContin expires in August 2027.

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### 7. Is this a short-term situation?

The supply will be limited and likely sporadic.

## 8. Is Purdue providing guidance for pharmacists, physicians, and nurses to give patients and caregivers information about the changes?

Purdue's Medical Services department can answer healthcare professional and patient questions about prescribing, dispensing, or taking OxyContin<sup>®</sup> and can be contacted at (888) 726-7535.

#### 9. Will generic versions of OxyContin be sold as a result of patent settlements?

Yes. As a result of settlements with several generic manufacturers, a limited amount of generic oxycodone extended-release will be available and the supply will be limited and likely sporadic.

## 10. What is the status of litigation with Teva to market their generic formulation?

Purdue does not comment on ongoing litigation.

## 11. Which generic companies will be selling authorized generics and how much authorized generic will they be selling?

Our settlements are confidential. Generic companies will likely be contacting their customers.

## 12. Will all strengths of authorized generic oxycodone ER be available?

Currently, there will not be authorized generics of 15 mg, 30 mg, and 60 mg strengths.

## 13. Will it be distributed to all wholesalers?

We cannot speculate on how generic manufacturers will distribute their products.

## 14. When will it be distributed to wholesalers?

We cannot speculate on the timing of the distribution of their products.



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#### 15. Over what period of time will authorized generics be available?

Pursuant to settlement agreements with Purdue, the companies selling authorized generics will be able to supply product for several years.

#### 16. What if a pharmacy can't get the generic?

We cannot speculate on how generic manufacturers will distribute their products. Purdue has the capacity to meet all demand with its branded product OxyContin<sup>®</sup>. We will work with wholesalers, retailers, and other customers to ensure that patients have appropriate access to OxyContin.

#### 17. Will this affect pharmacy reimbursement for OxyContin?

We cannot speculate on the effect on reimbursement.

#### 18. Who will be stocking generic oxycodone ER?

We cannot speculate on which pharmacies will be stocking generic oxycodone ER.

## 19. If an HCP wants to ensure their patients receive branded OxyContin, what additional steps can they take when prescribing?

As always, HCPs can either write DAW or Brand Medically Necessary on the prescription. This will depend on individual state guidelines.

#### 20. Does authorized generic oxycodone ER have abuse-deterrent properties?

Yes, the authorized generic versions of oxycodone ER contain the same abusedeterrent properties as branded OxyContin.

#### 21. Will OxyContin Savings Cards work for generic oxycodone ER?

No. OxyContin Savings Cards will only apply to branded OxyContin prescriptions.

#### 22. Will bonus be paid for authorized generic prescriptions?

Yes. The retail portion of Incentive Compensation Plan will include authorized generic prescription volume.



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