


HEALTHCARE

## **Indication Expansion**

Opportunities for successful lifecycle management

By Alison Sahoo

 [Table of Contents](#)

## **Alison Sahoo**

Alison Sahoo is a pharmaceutical industry analyst with more than 10 years of experience researching the development of medicines and medical devices. She holds a B.S. in Physics from McGill University and an M.B.A. in International Business from Rutgers University.

Copyright © 2007 Business Insights Ltd  
This Management Report is published by Business Insights Ltd. All rights reserved.  
Reproduction or redistribution of this Management Report in any form for any purpose is expressly prohibited without the prior consent of Business Insights Ltd.

The views expressed in this Management Report are those of the publisher, not of Business Insights. Business Insights Ltd accepts no liability for the accuracy or completeness of the information, advice or comment contained in this Management Report nor for any actions taken in reliance thereon.

While information, advice or comment is believed to be correct at the time of publication, no responsibility can be accepted by Business Insights Ltd for its completeness or accuracy.

# Table of Contents

## Indication Expansion

<b>Executive Summary</b>	<b>10</b>	
<b>Introduction</b>	<b>10</b>	
<b>Extension to related indications</b>	<b>11</b>	
<b>Extension to new applications</b>	<b>12</b>	
<b>Pediatric and special population extensions</b>	<b>13</b>	
<b>Extension of usage conditions</b>	<b>14</b>	
<b>Comparison of indication expansion strategies</b>	<b>15</b>	
<b>Chapter 1</b>	<b>Introduction</b>	<b>18</b>
<b>Summary</b>		<b>18</b>
<b>The importance of indication expansion</b>		<b>19</b>
<b>When an indication expansion is appropriate</b>		<b>19</b>
<b>Types of indication expansion</b>		<b>22</b>
Expanded drug usage conditions		22
Extension to related indications		23
Extension to additional indications		23
<b>Prerequisites for a successful indication expansion</b>		<b>25</b>
<b>Objectives of indication expansion</b>		<b>26</b>
<b>Benefits of indication expansion</b>		<b>27</b>
<b>Building additional revenue streams for a drug</b>		<b>29</b>
<b>Mitigating the effects of patent expiration</b>		<b>30</b>
The value of patents		30
Types of patents		31
Cost containment and the rise of generics		32
United States		32
United Kingdom		35
Germany		36
France		36
Italy		37
Spain		37

Impact on drug revenues	38
Expiring patents on blockbusters	39
Patent challenges	40
Case study: Lipitor	40
<b>Limitations of indication expansion</b>	<b>42</b>
<b>Trends in indication expansion</b>	<b>44</b>
Indication Removal	45
<b>Conclusion</b>	<b>45</b>
<b>Chapter 2</b>	<b>Extension to related indications</b>
	<b>48</b>
<b>Summary</b>	<b>48</b>
<b>Introduction</b>	<b>49</b>
<b>Treatment-prevention extensions</b>	<b>49</b>
Disease severity extensions	50
Case study: Aricept	52
Extensions to disease variants	53
Case study: Hycamtin	56
<b>When an indication extension is appropriate</b>	<b>57</b>
<b>Objectives of indication extension</b>	<b>58</b>
<b>Benefits of indication extension</b>	<b>59</b>
<b>Limitations of indication extension</b>	<b>62</b>
<b>Conclusion</b>	<b>64</b>
<b>Chapter 3</b>	<b>Extension to new applications</b>
	<b>66</b>
<b>Summary</b>	<b>66</b>
<b>Introduction</b>	<b>67</b>
<b>When a new application extension is appropriate</b>	<b>69</b>
New application extensions within drug families	70
Case study: Acomplia	70
<b>Objectives of new application extension</b>	<b>73</b>
<b>Benefits of new application extension</b>	<b>74</b>
Repositioning	75
Case Study: Lyrica	77
Case Study: Botox	79
<b>Limitations of new application extension</b>	<b>82</b>
<b>Conclusion</b>	<b>85</b>

## **Chapter 4                      Pediatric and special population extensions                      88**

<b>Summary</b>	<b>88</b>
<b>Introduction</b>	<b>89</b>
<b>Pediatric extensions</b>	<b>91</b>
<b>Gender-based extensions</b>	<b>93</b>
Geriatric extensions	93
<b>When a pediatric or special population extension is appropriate</b>	<b>95</b>
<b>Objectives of pediatric and special population extensions</b>	<b>95</b>
<b>Benefits of pediatric and special population extensions</b>	<b>96</b>
United States	97
Pediatric Research Equity Act of 2003	98
Chances of Pediatric Exclusivity Renewal in 2007	99
Europe	100
Case study: Claritin and Zyrtec	100
<b>Limitations of pediatric and special population extensions</b>	<b>102</b>
Case study: Norvasc	103
<b>Conclusion</b>	<b>105</b>

## **Chapter 5                      Extension of usage conditions                      108**

<b>Summary</b>	<b>108</b>
<b>Introduction</b>	<b>109</b>
<b>Monotherapy extensions</b>	<b>111</b>
Case Study: Topamax	112
Combination therapy extensions	113
Other usage extensions	115
<b>When a usage extension is appropriate</b>	<b>116</b>
<b>Objectives of usage extension</b>	<b>119</b>
<b>Benefits of usage extension</b>	<b>119</b>
Case study: Femara	120
<b>Limitations of usage extension</b>	<b>122</b>
Case study: torcetrapib	122
<b>Conclusion</b>	<b>124</b>

<b>Chapter 6</b>	<b>Comparison of indication expansion strategies</b>	<b>126</b>
<b>Summary</b>		<b>126</b>
<b>Introduction</b>		<b>127</b>
<b>Conditions under which each indication expansion strategy is appropriate</b>		<b>127</b>
<b>Comparative benefits of each indication expansion strategy</b>		<b>129</b>
<b>Comparative limitations of each indication expansion strategy</b>		<b>131</b>
<b>Combining indication expansion strategies</b>		<b>133</b>
Case Study: Singulair		134
Case Study: Taxotere		136
<b>Conclusion</b>		<b>139</b>
<b>Chapter 7</b>	<b>Appendix</b>	<b>142</b>
<b>Research methodology</b>		<b>142</b>
<b>Index</b>		<b>143</b>

# List of Figures

Figure 2.1:	Breakdown of new indication launches by therapeutic Area, 2005	21
Figure 2.2:	Comparison of drug development costs by strategy	28
Figure 3.3:	Disease characteristics supporting indication extension for disease variants	55
Figure 4.4:	Botox indications and revenues, 2000 – 2006	81
Figure 4.5:	Pricing opportunities and threats for a new drug indication	84
Figure 5.6:	Timeline of Zyrtec & Claritin US pediatric extensions, 1994 – 2006	101
Figure 7.7:	Comparative appropriateness of indication expansion strategies	128
Figure 7.8:	Comparative benefits of indication expansion strategies	130
Figure 7.9:	Comparative limitations of indication expansion strategies	132
Figure 7.10:	Benefits vs. limitations for indication expansion strategies	133
Figure 7.11:	Singulair indications and revenues, 2002 – 2006	136

# List of Tables

Table 2.1:	Selected indication expansions for US commercialized drugs	20
Table 2.2:	Revenues and patent expirations for selected companies' blockbusters, 2006	39
Table 3.3:	Selected indication extensions for US commercialized drugs	51
Table 3.4:	Impact on global revenues of indication extensions of selected drugs	60
Table 3.5:	Selected indication extension initiatives for US commercialized drugs, 2007	62
Table 4.6:	Selected new application extensions for US commercialized drugs	68
Table 4.7:	Approved and non-approved indications for anti-depressants in the US, 2007	71
Table 4.8:	Impact on global revenues of new additional extensions of selected drugs	75
Table 4.9:	Selected repositioning specialists	77
Table 4.10:	Selected new application extension initiatives for US commercialized drugs	79
Table 5.11:	Selected new application extension initiatives for US commercialized drugs	90
Table 5.12:	Non-approved pediatric usage for US commercialized drugs	92
Table 6.13:	Selected usage extensions for US commercialized drugs	110
Table 6.14:	Selected usage extension initiatives for US commercialized drugs, 2007	118
Table 7.15:	Taxotere indication expansions, 1999 - 2006	138