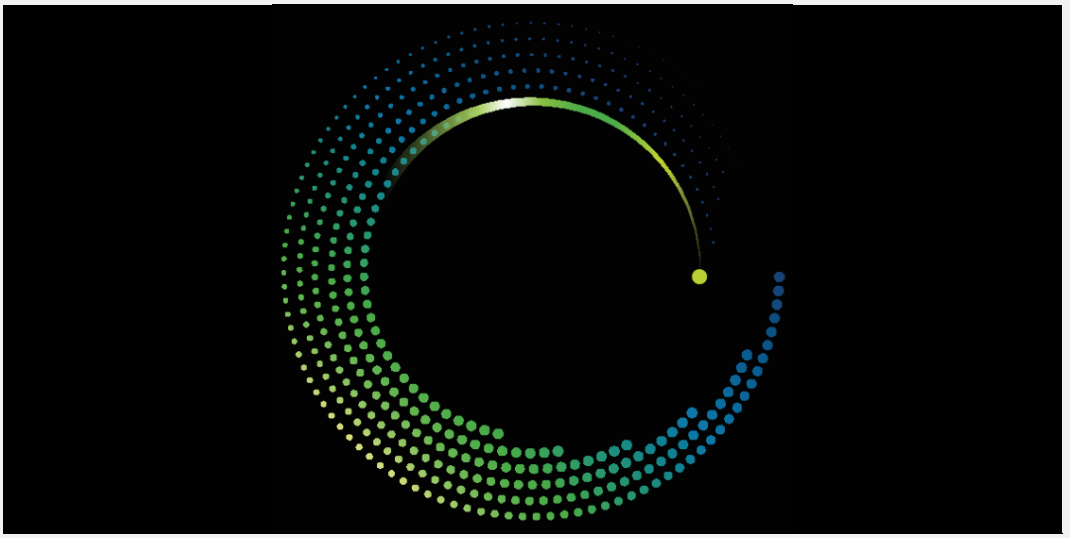
Deloitte.

MAKING AN IMPACT THAT MATTERS since 1845

Singapore | Tax & Legal | 27 June 2024



Tax Bytes

Concise insights to keep you ahead

Trusted. Transformational. Together.

Greetings from your Tax & Legal team at Deloitte Singapore.

We are pleased to update you on the following:

Pharmaceutical Manufacturing Industry—Tax Treatment of Research & Development and Intellectual Property-Related Expenditure (fourth edition)

On 20 March 2024, the Inland Revenue Authority of Singapore (IRAS) published the fourth edition of e-Tax Guide: Pharmaceutical Manufacturing Industry: Tax Treatment of Research & Development and Intellectual Property-Related Expenditure.

It replaces the third edition which was published on 20 March 2018.

The fourth edition of the e-Tax Guide has been updated to:

- incorporate editorial changes and modifications that accurately reflect the renumbering of specific sections (Sections 14D, 14DA and 37B to Sections 14C, 14D and 37A respectively) as a result of the renumbering and citation of the Income Tax Act 1947 (2020 Revised Edition);
- reflect the extension of the research and development (R&D) tax measures under Sections 14C and 14D to Year of Assessment (YA) 2028 as a result of the Income Tax (Amendment) Act 2023 (Act 30 of 2023), passed on 30 October 2023 (see our commentary here);
- clarify the different types of R&D tax deductions that are available under Sections 14C and 14D from YA 2019 to YA 2028 in paragraph 4.2;

- reflect the deletion of paragraph 4.3 as a result of the legislative changes and phasing out of the Productivity and Innovation Credit Scheme (PIC);
- reflect the introduction of the Enterprise Innovation Scheme in paragraphs 4.2 and 5.1; and
- clarify in Annex A which stage(s) of a typical value chain of a pharmaceutical manufacturing company would be treated as R&D.

No.	Change	Description of change	Comments
1	**R&D phase definition clarified**	The updated e-Tax guide explicitly defines which stages of a typical pharmaceutical manufacturing company value chain would fall within the R&D phase for tax purposes.	The updated Annex A explicitly states that R&D typically concludes after Stage 7. This demarcation appears to suggest that R&D would usually conclude after Stage 7 and further suggests that activities from Stage 8 (Commercial Manufacture) onwards are not considered R&D. This contrasts with the previous understanding, where the distinction between R&D and commercial manufacture stages might not have been as expressly stated.
2	**Stage 8 (Commercial Manufacture)**	The updated Annex no longer explicitly discuss the specifics of Stage 8, which involves the commercial manufacture of the drug, including the primary and secondary manufacturing phases.	This omission suggests that the focus of the new guidelines is on the earlier stages of drug development rather than providing details on the manufacturing stage.
3	**Classification of clinical trials**	In the updated Annex A, clinical trials conducted before the company secures manufacturing permission are considered part of R&D. This includes trials aimed at verifying the drug's efficacy and safety. However, clinical trials that occur post-approval for the purpose of monitoring long-term effects are not classified as R&D, unless they contribute to further scientific or technological advancements.	This change introduces a more selective approach to classifying post-approved clinical trials. While clinical trials conducted after the drug has been approved for manufacture were generally considered part of ongoing research and development efforts, the new guidelines specify that only those trials which aim for and achieve further scientific or technological advancements will be considered R&D. This implies that post-approval trials primarily conducted for regulatory compliance, marketing development, or patient monitoring etc., will not be classified as R&D unless they contribute to significant scientific or technological progress.

	This distinction reflects a more strategic allocation of R&D classification, emphasising the intention behind and outcomes of post-approval clinical trials. It suggests a shift towards recognising and categorising activities based on their contribution to scientific knowledge and technological innovation, rather than their chronological placement in the drug development timeline.

Closing remarks

Whilst most of the changes are primarily editorial due to legislative updates, the main revision introduced in the fourth edition of the e-Tax Guide is the clear inclusion of Stage 7 within the R&D phase, underscoring the critical nature of process development in the drug development lifecycle. This change highlights the continuity and comprehensive scope of R&D activities up to the threshold of commercial manufacturing.

Read more

Contacts

Should you have any comments or questions arising from this newsletter, please contact either the listed contacts below, or any member of the **Singapore Tax & Legal team**.

Daniel Ho
Head of Tax
Deloitte Singapore

+65 6216 3189
danho@deloitte.com

Chua Kong Ping
Tax Partner
Deloitte Singapore

+65 6800 2966
kchua@deloitte.com

Lee Tiong Heng
Global Investment & Innovation Incentives Leader
Deloitte Southeast Asia

+65 6216 3262
thlee@deloitte.com

Yvaine Gan
Global Investment & Innovation Incentives Leader
Deloitte Singapore

+65 6531 5090
yvgan@deloitte.com

Eugene Penafort
Global Investment & Innovation Incentives Director
Deloitte Singapore

+65 6530 5511
epenafort@deloitte.com

Dbriefs

Dbriefs
A series of live, on-demand and interactive webcasts focusing on topical tax issues for business executives.

Tax@hand
Latest global and regional tax news, information, and resources.

Get in touch

Deloitte Singapore

Deloitte refers to one or more of Deloitte Touche Tohmatsu Limited ("DTTL"), its global network of member firms, and their related entities (collectively, the "Deloitte organization"). DTTL (also referred to as "Deloitte Global") and each of its member firms and related entities are legally separate and independent entities, which cannot obligate or bind each other in respect of third parties. DTTL and each DTTL member firm and related entity is liable only for its own acts and omissions, and not those of each other. DTTL does not provide services to clients. Please see www.deloitte.com/about to learn more.

Deloitte Asia Pacific Limited is a company limited by guarantee and a member firm of DTTL. Members of Deloitte Asia Pacific Limited and their related entities, each of which is a separate and independent legal entity, provide services from more than 100 cities across the region, including Auckland, Bangkok, Beijing, Bengaluru, Hanoi, Hong Kong, Jakarta, Kuala Lumpur, Manila, Melbourne, Mumbai, New Delhi, Osaka, Seoul, Shanghai, Singapore, Sydney, Taipei and Tokyo.

About Deloitte Singapore
In Singapore, tax and immigration services are provided by Deloitte Tax Solutions Pte. Ltd. and other services (where applicable) may be carried out by its affiliates.

Deloitte Tax Solutions Pte. Ltd. (Unique entity number: 202008330C) is a company registered with the Accounting and Corporate Regulatory Authority of Singapore.

This communication contains general information only, and none of DTTL, its global network of member firms or their related entities is, by means of this communication, rendering professional advice or services. Before making any decision or taking any action that may affect your finances or your business, you should consult a qualified professional adviser.

No representations, warranties or undertakings (express or implied) are given as to the accuracy or completeness of the information in this communication, and none of DTTL, its member firms, related entities, employees or agents shall be liable or responsible for any loss or damage whatsoever arising directly or indirectly in connection with any person relying on this communication.